

EXHIBIT A-65

Alice Stills, on her own behalf and as Parent and
Natural Guardian of M.E., a minor

Plaintiffs

v.

MEAD JOHNSON & COMPANY, LLC, et al.

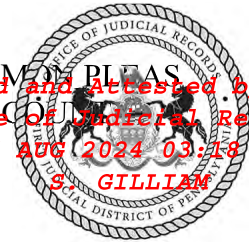
Defendants.

COURT OF COMMON PLEAS
PHILADELPHIA

CIVIL DIVISION

MARCH TERM, 2022

NO. 2617



Filed and Attested by the
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06 AUG 2024 03:18 pm
S. GILLIAM

ORDER

AND NOW, this day of 2024, upon consideration of the Preliminary Objections of Defendants the Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital and the Trustees of the University of Pennsylvania d/b/a Penn Medicine to Plaintiffs' Second Amended Complaint, and any Response thereto, it is hereby **ORDERED** that the Preliminary Objections are **SUSTAINED**. It is further **ORDERED** that all claims against Defendants the Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital and the Trustees of the University of Pennsylvania d/b/a Penn Medicine are hereby **DISMISSED** with prejudice.

BY THE COURT:

J.

Alice Stills, on her own behalf and as Parent and
Natural Guardian of M.E., a minor

Plaintiffs

v.

MEAD JOHNSON & COMPANY, LLC, et al.

Defendants.

COURT OF COMMON PLEAS
PHILADELPHIA COUNTY

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MARCH TERM, 2022
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ALTERNATIVE ORDER

AND NOW, this day of 2024, upon consideration of the Preliminary Objections of Defendants the Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital and the Trustees of the University of Pennsylvania d/b/a Penn Medicine to Plaintiffs' Second Amended Complaint, and any Response thereto, it is hereby **ORDERED** that the Preliminary Objections are **SUSTAINED**. It is further **ORDERED** that:

1. Count VI of Plaintiffs' Amended Complaint is **DISMISSED** with prejudice;
2. Count VII of Plaintiffs' Amended Complaint is **DISMISSED** with prejudice;
3. Plaintiffs' claims for punitive damages as to Defendants the Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital and the Trustees of the University of Pennsylvania d/b/a Penn Medicine are **DISMISSED** with prejudice, along with all allegations of oppressive, reckless, malicious and/or fraudulent conduct; and
4. Plaintiff Alice Stills' claims in her own right are **DISMISSED** with prejudice.
5. Plaintiffs' Second Amended Complaint is **STRICKEN** for lack of an appropriate verification.

BY THE COURT:

J.

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Pennsylvania d/b/a Penn Medicine*

Alice Stills, on her own behalf and as Parent and
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**PRELIMINARY OBJECTIONS OF DEFENDANTS THE PENNSYLVANIA HOSPITAL
OF THE UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM AND THE
TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA
TO PLAINTIFFS' SECOND AMENDED COMPLAINT**

Defendants the Pennsylvania Hospital of the University of Pennsylvania Health System (“Pennsylvania Hospital”) and the Trustees of the University of Pennsylvania (hereinafter “Moving Defendants”) hereby preliminarily object to Plaintiffs’ Second Amended Complaint, and, in support thereof, aver as follows:

I. FACTUAL AND PROCEDURAL HISTORY

1. Plaintiffs instituted this action via the filing of a Complaint on March 24, 2022 against Moving Defendants as well as Co-Defendants Mead Johnson & Company, LLC, Mead Johnson Nutritional Company (collectively referred to as “Mead Johnson”) and Abbott

Laboratories (“Abbott”). A true and correct copy of Plaintiffs’ Complaint is attached hereto as Exhibit “A.”

2. On June 9, 2023, Moving Defendants filed preliminary objections to Plaintiffs’ Complaint, seeking the Court to: 1) dismiss Counts VI and VII for lack of specificity; 2) strike Plaintiffs’ Complaint in its entirety for insufficient specificity of the facts and alleged injuries; 3) strike Plaintiffs’ claims for punitive damages for failure to plead sufficient facts; and 4) strike Plaintiff-parent’s claims for failure to state a cause of action, for failure to plead separate causes of action, and based on the applicable statute of limitations. A true and correct copy of Preliminary Objections to Plaintiffs’ Complaint is attached hereto as Exhibit “B.”

3. On September 8, 2023, Plaintiffs filed an Amended Complaint, which still contained substantially all of the fatal flaws that Moving Defendants raised in their first set of Preliminary Objections. A true and correct copy of Plaintiffs’ Amended Complaint is attached hereto as Exhibit “C.”

4. Thus, on September 27, 2023, Moving Defendants filed Preliminary Objections to Plaintiffs’ Amended Complaint. A true and correct copy of Moving Defendants’ Preliminary Objections to Plaintiffs’ Amended Complaint is attached hereto as Exhibit “D.”

5. On March 20, 2024, the Court sustained Moving Defendants’ preliminary objections, and ordered Plaintiffs to file an Amended Complaint “setting forth their claims for professional negligence and damages with specificity.” A true and correct copy of the Court’s Order is attached hereto Exhibit “E.”

6. On July 17, 2024, Plaintiffs filed a Second Amended Complaint, which includes some additional factual allegations, but the same fatal flaws are still present. A true and correct copy of Plaintiffs’ Second Amended Complaint is attached hereto as Exhibit “F.”

7. Plaintiffs have filed a slew of essentially identical lawsuits against Pennsylvania Hospital and other hospitals in Philadelphia based on claims relating to alleged ingestion of cow's milk-based infant formula by premature infants following their birth.¹

8. Plaintiffs allege that the Plaintiff-minor, M.E., was diagnosed with necrotizing enterocolitis (NEC), a gastrointestinal disorder that premature infants are at increased risk to develop. *See* Exhibit F, ¶¶ 16, 22. Plaintiffs allege that premature infants fed with their mother's breast milk or donor breast milk are at decreased risk of developing NEC as compared with infants given cow's milk-based infant formula and fortifiers added to human milk.²

9. In addition to asserting product liability claims against the infant formula manufacturers Mead Johnson and Abbott, Plaintiffs have alleged that Moving Defendants are liable based on theories of failure to warn and corporate liability.³

10. Plaintiffs aver that M.E. was born prematurely on September 28, 2007 and that "upon information and belief" she "was fed Similac and/or Enfamil cow's milk-based products by staff at Pennsylvania Hospital after his birth." *Id.*, ¶¶ 11-12.

11. Plaintiffs allege that "[u]pon information and belief, M.E. developed NEC after ingesting Defendant Manufacturers' products." *Id.*, ¶ 13.

¹ Lawsuits involving identical claims have been filed against the Hospital of the University of Pennsylvania, Temple University Hospital, Albert Einstein Medical Center, Jefferson Abington Hospital and Thomas Jefferson University Hospital.

² Although Plaintiffs aver in the Second Amended Complaint that NEC is caused by cow's milk-based infant formula and fortifiers, as discussed *infra* and in the accompanying Memorandum of Law, Plaintiffs do not cite any study or statement in the Second Amended Complaint that indicates NEC is caused by cow's milk-based products.

³ As is discussed below, infant formulas are regulated by the United States Food and Drug Administration and are required to include specified vitamins and nutrients, including infant formulas intended for low birth weight infants. The FDA does not restrict the use of cow's milk-based infant formula for premature or low birth weight infants. Plaintiff's contention that cow's milk-based infant formula should never be given to premature infants is not supported by the FDA.

12. Plaintiffs aver that beginning on September 29, 2007, M.E. was fed with mother's breast milk which was fortified with bovine-based human milk fortifier which "upon information and belief was manufactured by" Defendant Abbott Laboratories and/or Defendant Mead Johnson. *Id.*, ¶ 14.

13. Plaintiffs further aver that "no later than October 29, 2007," Dr. Thomas Mollen "revised his nutritional orders" to start feeding M.E. Defendant Abbott's "'Special Care' bovine based formula which M.E. was ultimately fed for a total of 31 days while under the care of Pennsylvania Hospital." *Id.*, ¶ 15.

14. According to Plaintiffs, M.E. was diagnosed with stage II-B Medical NEC on November 2, 2007, and was subsequently transferred to Children's Hospital of Philadelphia, where M.E. received treatment from November 2 to November 8, 2007. *Id.*, ¶ 16.

15. Plaintiff allege that M.E. was discharged from CHOP on November 8, 2007 and returned to Pennsylvania Hospital, where M.E. was given two different products manufactured by Abbott until M.E. was discharged on December 5, 2007. *Id.*, ¶¶ 17, 19.

16. Plaintiffs generally allege that "[a]s a result of the Stage II-B Medical NEC diagnosis," M.E. "experienced developmental delay, including but not limited to neurodevelopmental impairment." *Id.*, ¶ 20.

17. Moving Defendants Preliminarily Object to Plaintiffs' Second Amended Complaint for the reasons stated below and as set forth in the accompanying Memorandum of Law, which is incorporated herein by reference.

II. ARGUMENT

A. DEMURRER TO COUNT VI: FAILURE TO WARN

18. Pursuant to Pa.R.C.P. 1028(a)(4), a party may file preliminary objections to a complaint, in the nature of a demurrer, for legal insufficiency in a pleading. A court should grant a demurrer where, accepting as true all well pled facts, a legal cause of action cannot be maintained upon those facts. Pa.R.C.P. 1028(a)(4); *See also, Willet v. Pennsylvania Med. Catastrophe Loss Fund*, 702 A.2d 850, 853 (Pa. 1997).

19. In alleging a failure to warn claim against Moving Defendants, Plaintiffs appear to conflate a cause of action for negligent failure to warn, with a cause of action for failing to obtain informed consent. Under either theory, Count VI is legally deficient and must be dismissed.

- i. **Plaintiffs failed to state a cause of action for negligent failure to warn because Plaintiffs' baseless assertions that Moving Defendants are "suppliers" and that the cow's milk-based products at issue were unreasonably dangerous, are not support with sufficient factual allegations.**

20. Plaintiffs allege in Count VI of the Second Amended Complaint that Moving Defendants "as purchaser, supplier, and/or distributor of the products at issue in the litigation" owed Plaintiffs and the public a duty to provide products that were free of unreasonable risk of harm. *See* Exhibit F, ¶ 154.

21. Taking the facts as pleaded by Plaintiffs as true, Plaintiffs have failed to state a claim for negligent failure to warn against Moving Defendants because they have failed to plead sufficient facts to support any assertion that Moving Defendants are "suppliers" and that the products at issue were "unreasonably dangerous."

22. Pennsylvania courts have adopted Restatement (Second) of Torts § 388 in cases involving a claim of negligent failure to warn.” *Dauphin Deposit Bank & Trust Co. v. Toyota Motor Corp.*, 596 A.2d 845, 850 (Pa. Super. 1991).

23. Section 388 governs this cause of action, and provides:

One who supplies directly or through a third person a chattel for another to use is subject to liability to those whom the supplier should expect to use the chattel with the consent of the other or to be endangered by its probable use, for physical harm caused by the use of the chattel in the manner for which and by a person for whose use it is supplied, if the supplier

- (a) knows or has reason to know that the chattel is or is likely to be dangerous for the use for which it is supplied, and
- (b) has no reason to believe that those for whose use the chattel is supplied will realize its dangerous condition, and
- (c) fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be dangerous.

24. First, Moving Defendants had no duty to warn of the nature of cow’s milk-based products under § 388 because medical providers are not “supplying” a product to a patient within the stream of commerce. Thus, Count VI should be dismissed for this reason alone.

25. Additionally, Plaintiffs must aver sufficient facts demonstrating the Defendant Manufacturers’ products are unreasonably dangerous for their intended use, triggering Moving Defendants’ duty to warn, which Plaintiffs have failed to do.

26. “The threshold inquiry in all products liability cases is whether there is a defect which rendered the product unreasonably dangerous.” *Weiner v. American Honda Motor Co., Inc.*, 718 A.2d 305, 307 (Pa. Super. 1998).

27. “A product is defective when it is not safe for its intended use, i.e., the product left the supplier's control lacking any element necessary to make it safe for its intended use.” *Id.* at 308.

28. At the outset of their Second Amended Complaint, Plaintiffs appropriately acknowledge that “[p]reterm and low-birth-weight infants are *especially susceptible to NEC*.” See Exhibit F at ¶ 22 (emphasis added). Following this, Plaintiffs make the core claim of their Second Amended Complaint – that cow’s milk-based feeding products cause NEC in preterm and low birth weight infants – and that “[e]xtensive scientific research, including numerous randomized controlled trials” confirm this claim. *See id.*

29. However, Plaintiffs do not allege any facts to support their claim that “scientific research” demonstrates that cow’s milk-based feeding products cause NEC in preterm and low birth weight infant.

30. Plaintiffs appear to base this core claim on flawed studies cited in the original Complaint that Plaintiffs subsequently omitted in their Amended Complaint and Second Amended Complaint.

31. In their original Complaint, in support of their assertion that the products at issue were dangerous to M.E., Plaintiffs referenced five studies comparing cow’s milk-based products to breast milk, a Surgeon General report on the subject, and a statement by the American Academy of Pediatrics. *See Exhibit A, ¶¶ 17-22.*

32. As Moving Defendants argued in their Preliminary Objections to Plaintiffs’ original Complaint, the studies cited by Plaintiffs demonstrate only, assuming the facts as true as stated by Plaintiffs, that premature infants are at high risk of NEC, and that feeding such infants with breast milk may be better at reducing the risk of NEC than cow’s milk-based alternatives. *See Exhibit A, ¶¶ 17-22.*

33. Plaintiffs appear to concede that the aforementioned studies did not support their allegations because Plaintiffs removed all references to the studies and deleted paragraphs 17 through 22 in their Amended Complaint, and again in their Second Amended Complaint.

34. In lieu of relying on the studies originally cited by Plaintiffs in their Complaint, Plaintiffs generally allege in their Second Amended Complaint that “scientific evidence” exists demonstrating that cow’s milk-based products cause NEC. *See, e.g.*, Exhibit F, ¶¶ 27-30. However, Plaintiffs do not plead any additional facts to support their assertion that such “scientific evidence” exists.

35. Further, Plaintiffs’ baseless assertion that the cow’s milk-based products at issue were “unreasonably dangerous” is incompatible with the reality that such products are carefully regulated by the United States Food and Drug Administration (“FDA”), and Plaintiffs are not alleging that Moving Defendants did anything contrary to the applicable federal regulations.

36. The Infant Formula Act of 1980 (“IFA”) was enacted “to assure the safety and nutrition of infant formulas.” *See* Pub. L. No. 96-359, 94 Stat. 1190.

37. The IFA and its implementing regulations outline the requirements that infant formula must meet, including how infant formula is made, its contents and ingredients, and the labels used on its packages. *See* 21 U.S.C. § 350a; 21 C.F.R. §§ 106-07.

38. Neither the IFA nor the regulations exclude cow’s milk as an ingredient, and many infant formulas for sale include cow’s milk. 21 C.F.R. § 106.3 (“infant formula” is a “food for infants by reason of its *simulation* of human milk”) (emphasis added). 21 U.S.C. § 350a; 21 C.F.R. §§ 107.50.

39. Plaintiffs have not alleged any facts that would justify overlooking an entire regulatory framework dedicated to ensuring the safety of infant formula in the United States.

40. Thus, Plaintiffs have failed to state a claim for negligent failure to warn against Moving Defendants as they have failed to state facts to establish that cow's milk-based products is unreasonably dangerous for its intended purpose.

41. Alternatively, even if the products at issue here can be viewed as unreasonably dangerous, Plaintiffs still have failed to plead sufficient facts that Moving Defendants are a supplier of products that are ancillary to the medical services provided to Plaintiffs.

ii. **Count VI is also deficient to the extent Plaintiffs' "failure to warn" claim is based on an alleged failure to obtain informed consent.**

42. Plaintiffs' failure to warn claim is similarly precluded to the extent that Plaintiffs are alleging that Defendants, in providing medical care to Plaintiff-minor, failed to obtain Plaintiff-parent's consent to the use of cow's milk-based products and failed to warn of the purported risks and alternatives of such products.

43. Plaintiffs are impliedly asserting that Moving Defendants failed to obtain Plaintiff-parent's informed consent as to whether she should use cow's milk-based products to feed her child, based on the alleged risks of cow's milk-based products. However, such a claim is not cognizable under Pennsylvania law.

44. Claims for informed consent in medical malpractice actions are governed by the Medical Care Availability and Reduction of Error Act, which provides as follows:

(a) **Duty of Physicians.**--Except in emergencies, a physician owes a duty to a patient to obtain the informed consent of the patient or the patient's authorized representative prior to conducting the following procedures:

- (1) Performing surgery, including the related administration of anesthesia.
- (2) Administering radiation or chemotherapy.
- (3) Administering a blood transfusion.

(4) Inserting a surgical device or appliance.

(5) Administering an experimental medication, using an experimental device or using an approved medication or device in an experimental manner.

(b) Description of procedure.--Consent is informed if the patient has been given a description of a procedure set forth in subsection (a) and the risks and alternatives that a reasonably prudent patient would require to make an informed decision as to that procedure. The physician shall be entitled to present evidence of the description of that procedure and those risks and alternatives that a physician acting in accordance with accepted standards of medical practice would provide.

40 P.S. §1303.504 (emphasis added).

45. The language of the statute above reveals two significant tenets.

46. The first is that the informed consent statute does not apply to the use of cow's milk-based products in feeding premature infants, since feeding is not a "procedure."

47. Informed consent has not been extended to any type of therapeutic treatment involving an ingestible therapeutic drug, which the court defined as "an ongoing treatment upon examination by the treating physician, where any change of condition can be diagnosed and controlled." *Boyer v. Smith*, 497 A.2d 646, 648 (Pa. Super. 1985).

48. The Superior Court ruled that the informed consent doctrine is premised upon the legal theory that the performance of a medical procedure without a patient's informed consent constitutes a technical assault or battery, and that merely prescribing an oral medication, which does not involve touching, does not amount to battery and therefore, obtaining informed consent is not required under those circumstances. *Id.* at 649.

49. The same principles clearly apply to infant feeding because, just like when a provider administers medication, the provider is not engaged in "touching" when formula or human milk fortifiers are ordered for an infant's feeding.

50. Thus, there is no basis for Plaintiffs to contend that Plaintiff-parent's consent was required for the use of cow's milk-based products to feed her infant, including warning her of the risks or alternatives of same.

51. Second, the informed consent statute only applies to physicians, not hospitals, in the context of medical procedures. *See* 40 P.S. § 1303.504; *see also Valles v. Albert Einstein Medical Center*, 805 A.2d 1232, 1239 (Pa. 2002) (holding that duty to obtain informed consent belongs “solely to the physician” and thus a medical facility cannot be vicariously liable for a failure to obtain informed consent); *Isaac v. Jameson Mem. Hosp.*, 932 A.2d 924, 930 (Pa. Super. 2007) (“Given the unique nature of the doctrine and its origins as a technical battery, hospitals cannot be held vicariously liable for a physician’s failure to obtain informed consent because ‘a medical facility cannot maintain control over this aspect of the physician-patient relationship.’”); *Kelly v. Methodist Hosp.*, 664 A.2d 148 (Pa. Super. 1995) (holding that generally only the physician who performs the operation on the patient has the duty of obtaining his consent for the procedure).

52. For these reasons, Moving Defendants cannot be held liable for a physician's failure to obtain proper informed consent, nor can they be liable for any alleged failure to obtain informed consent related to infant feeding, which is not a “procedure” under 40 P.S. § 1303.504.

53. Accordingly, it is respectfully requested this Court sustain Moving Defendants' Preliminary Objections to Count VI.

B. DEMURRER TO COUNT VII: CORPORATE LIABILITY OF HEALTH CARE PROVIDER

- i. **Moving Defendants cannot be held liable under a theory of corporate liability for failing to prevent the use of cow's milk-based products, which is regulated by the FDA and not precluded for use in premature or low birth weight infants.**

54. In *Thompson v. Nason Hospital*, 591 A.2d 703, 708 (Pa. 1991), the Pennsylvania Supreme Court recognized the doctrine of corporate liability, holding that a hospital may be found directly liable for negligence if it fails to meet *any* of the following four duties: (1) a duty to use reasonable care in the maintenance of safe and adequate facilities and equipment; (2) a duty to select and retain only competent physicians; (3) a duty to oversee all persons who practice medicine within its walls as to patient care; and (4) a duty to formulate, adopt and enforce adequate rules and policies to ensure quality care for patients.

55. Plaintiffs' corporate liability claim fails based on the same rationale as the claim for failure to warn, since both claims are based on the alleged failure to provide warnings to patients related to the use of cow's milk-based products.

56. Infant formula is regulated by the FDA, and there is no legal restriction on the use of cow's milk-based products for feeding of premature infants, as discussed *supra*.

57. Indeed, the Infant Formula Act expressly acknowledges that it is permissible to provide cow's-milk based products to low birth weight infants.

58. Further, as discussed above, Plaintiffs cannot demonstrate that cow's milk-based formula and fortifiers are unreasonably dangerous products.

59. Thus, there is no legal basis to contend that Moving Defendants can be held liable pursuant to a theory of corporate liability for failing to prevent the use of cow's milk-based products in the feeding of premature infants in the hospital.

ii. **Plaintiffs have not sufficiently pled facts to establish “systemic negligence” as required to bring a claim for corporate negligence.**

60. Courts considering the application of the duties set forth in *Thompson* have insisted on more than a simple finding of a negligent act by someone for whom the hospital is purportedly responsible. *Edwards v. Brandywine Hospital*, 652 A.2d 1382 (Pa. Super. 1995).

61. In considering whether the plaintiff could sustain corporate negligence claims based on these allegations, the *Edwards* court analyzed the *Thompson* decision and delineated the standards required to sustain such a claim:

The *Thompson* theory of corporate liability **will not be triggered every time something goes wrong in a hospital which harms a patient . . .** To establish corporate negligence, a plaintiff must show more than an act of negligence by an individual for whom the hospital is responsible. Rather, *Thompson* requires a plaintiff to show that the hospital itself is breaching a duty and is somehow substandard...*Thompson* contemplates a kind of ‘**systemic negligence**’...

Id. at 1386-87 (citations omitted and emphasis added).

62. Thus, corporate liability requires “more than individual acts of negligence.” *Id.* As noted by the court in *Edwards*, this reading of the Court’s opinion in *Thompson* is the only way to logically construe its holding, as hospitals are already held vicariously liable for the negligent acts of their employees and ostensible agents, while “*Thompson* requires a plaintiff to show that the **hospital itself** is breaching a duty and is somehow substandard.” *Id.* at 1387; *see also MacDonald v. Chestnut Hill Hosp.*, 2005 Phila. Ct. Com. Pl. LEXIS 273, 18 (Pa. C.P. 2005) (granting nonsuit to the hospital defendant where “[t]here was no evidence that protocols were routinely ignored to the detriment of patients or that the kind of systematic negligence on the part of CHH required by the *Edwards* decision was present.”)

63. Thus, a hospital may not be held liable via corporate negligence simply based on the alleged negligence of an individual health care provider.

64. Accordingly, even if Plaintiffs could establish that the use of cow's milk-based products was a breach of the standard of care by unidentified health care providers based on the specific circumstances of the Plaintiff-minor's case herein, which has not been pleaded by Plaintiffs considering the paucity of the allegations in the Second Amended Complaint, such evidence cannot support a finding of corporate liability.

65. For the reasons stated above, Count VII of Plaintiffs' Second Amended Complaint should be dismissed with prejudice.

iii. Plaintiffs are precluded from bringing a corporate negligence claim against Defendant Trustees of the University of Pennsylvania, which is merely a non-hospital, corporate parent of Pennsylvania Hospital.

66. Even assuming Plaintiffs had a viable corporate negligence claim against Pennsylvania Hospital, any such claim is precluded against the Trustees of the University of Pennsylvania since it is not a hospital.

67. The *Thompson* holding has been extended to HMOs and nursing home facilities, where it was determined that such entities performed similar functions as hospitals. *See Shannon v. Health America Pennsylvania, Inc.*, 718 A.2d 828 (Pa. Super. 1998); *Scampono v. Highland Park Care Center, LLC*, 57 A.3d 582 (Pa. 2012).

68. However, courts have routinely refused to extend the *Thompson* holding past such institutions to cover other entities, such as medical clinics and physician practice groups. *See Sutherland v. Monongahela Valley Hospital*, 856 A.2d 55, 62 (Pa. Super. 2004); *Dowhouer v. Judson*, 45 Pa. D. & C.4th 172, 180 (Pa.Com.Pl. 2000); *Brewer v. Geisinger Clinic, Inc.*, 45 Pa. D. & C.4th 215, 223 (Pa.Com.Pl. 2000); *Dibble v. Penn State Geisinger Clinic, Inc.*, 42 Pa. D. & C.4th 225 (Pa.Com.Pl. 1999); *Davis v. Gish*, 5 Pa. D. & C.5th 154, 159 (Pa.Com.Pl. 2007).

69. There is no legal basis for holding that the purported corporate parent of a hospital, such as the Trustees of the University of Pennsylvania, can be held liable under a theory of corporate negligence.

70. Indeed, the *Scampone* Court cautioned that the trial court should ensure that “multiple entities are not exposed to liability for breach of the same non-delegable duties.” 57 A.2d at 606-07.

71. Thus, the corporate negligence count against Trustees must be dismissed as a matter of law.

C. MOTION TO STRIKE PLAINTIFFS’ SECOND AMENDED COMPLAINT FOR INSUFFICIENT SPECIFICITY AS TO THE FACTS AND ALLEGED INJURIES

72. Pursuant to Pa.R.C.P. 1028(a)(3), a party may file preliminary objections in the nature of a motion to strike for insufficient specificity in a pleading.

73. A plaintiff’s Complaint is required to provide a defendant with notice of what the plaintiff’s claims are and the grounds upon which they rest, and the complaint must also formulate the issues by summarizing the facts essential to support the claims. *Alpha Tau Omega Fraternity v. The University of Pennsylvania*, 464 A.2d 1349, 1352 (Pa. Super. 1983) (*citations omitted*).

74. Pennsylvania Rule of Civil Procedure 1019(a) provides that “the material facts on which a cause of action or defense is based shall be stated in a concise and summary form.” Pa.R.C.P. 1019(a). As the Superior Court has noted,

Rule 1019(a) requires fact pleading. The purpose of 1019(a) is to require the pleader to disclose the material facts sufficient to enable the adverse party to prepare his case. **A complaint therefore must do more than give the defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests. It should formulate the issues by fully summarizing the material facts. Material facts are ultimate facts, i.e., those facts essential to support the claim. Evidence from which such facts may be inferred not only need not but should not be alleged. Allegations will withstand challenge under 1019(a) if (1) they contain**

averments of all of the facts a plaintiff will eventually have to prove in order to recover, and (2) they are sufficiently specific so as to enable defendant to prepare his defense.

Baker v. Rangos, 324 A.2d 498, 505-506 (Pa. Super. 1974) (citations and internal quotations omitted)(emphasis added).

75. Further, it is well established that, with regard to the description of injuries sustained by a plaintiff, the Complaint must be stated with sufficient particularity to put the defendant on notice of evidence that may be produced at trial. *Kelly v. Martino*, 99 A.2d 901 (Pa. 1953). **A plaintiff's Complaint must set forth the extent, nature, location and duration of the injuries suffered, and injuries that are permanent should be stated specifically.** *Miller v. Perrige*, 71 Pa. D. & C.2d 476, 479–80 (Pa. Com. Pl. 1975). *See, also, Kopan v. Hawk*, 14 Pa. D. & C.2d 713, 714 (Pa. Com. Pl. 1958) (“A catchall averment of “other injuries” is nothing more than a generalized averment under which any injuries whatever could be proved at the trial. Defendant would have no knowledge in advance of the trial of what they are.”)

76. Plaintiffs' Second Amended Complaint is deficient with regard to the specificity of the allegations of the relevant facts and injuries at issue in this case.

77. Of the 193 paragraphs in Plaintiffs' Second Amended Complaint, only ten paragraphs address material facts relating to the Plaintiff-minor's care and treatment, diagnosis and injuries, which are utterly insufficient to enable Moving Defendants to prepare their defenses. *See* Exhibit F, ¶¶ 11-20.

78. Plaintiffs' allegation that “upon information and belief,” the Plaintiff-minor was fed Similac **and/or** Enfamil after her birth (*Id.* at ¶ 13) does not comply with the fact-pleading requirements of Rule 1019(a), since such allegations do not provide Moving Defendants with

appropriate notice of the facts as to whether and when the Plaintiff-minor actually ingested those cow's milk-based products.

79. Additionally, Plaintiffs do not allege any factual basis to support their theory that cow's milk-based products caused M.E.'s NEC diagnosis, other than vague references to unidentified "scientific evidence."

80. Plaintiffs also fail to state sufficient facts concerning the nature of the injuries and the "developmental delay" that are alleged to have resulted from the diagnosis of NEC. Further, Plaintiffs fail to allege any factual basis to support a causal connection between the NEC and M.E.'s alleged developmental delay.

81. Plaintiffs' damages claim is not stated with particularity, is amorphous, vague, and open-ended. Pursuant to Pennsylvania pleading requirements, Moving Defendants should not be compelled to defend a claim for which the statement of injury is unspecified and subject to change.

82. These omissions are fatal defects. Therefore, Plaintiffs' Second Amended Complaint should be stricken in its entirety.

D. MOTION TO STRIKE PLAINTIFFS' CLAIMS FOR PUNITIVE DAMAGES

83. In the *Ad Damnum* clauses of Counts VI and VII of the Second Amended Complaint, Plaintiffs make baseless accusations that Moving Defendants engaged in outrageous, oppressive, reckless, malicious and/or fraudulent conduct that allegedly justify an award of punitive damages.

84. However, the Second Amended Complaint contains no specific allegations of conduct that would permit recovery of punitive damages as to Moving Defendants.

85. Rather, Plaintiffs merely allege that "upon information and belief" M.E. may have been given a cow's milk-based product following birth, absent any context to indicate that such an

action was inappropriate based on the specific issues involved in M.E.'s medical care and condition following birth.

86. For example, the Second Amended Complaint does not give any indication whether Plaintiff-parent refused or was unable to provide breast milk and provides no information as to discussions between her and any health care providers regarding the purported use of cow's milk-based products.

87. Plaintiff's allegations of oppressive, outrageous, malicious and similar conduct must be rejected as mere boilerplate. As discussed above, the FDA specifically approves the use of infant formula in care of low birth weight infants, with no restriction as to the use of cow's milk-based products for such infants.

88. Indeed, the fact that Plaintiffs have filed numerous lawsuits against at least five hospitals in Philadelphia based on identical claims belies the contention that Moving Defendants engaged in outrageous or malicious conduct in allegedly feeding the Plaintiff-minor with cow's milk-based products.

89. Absent specific factual allegations to justify the claim that the use of cow's milk-based products in M.E.'s case was extreme and outrageous, there is no basis for an award of punitive damages in this case.

90. Merely contending that punitive damages should be awarded with no supporting factual justification requires dismissal of the claim.

91. Since the purpose of punitive damages is not compensation of a plaintiff but punishment of the defendant and deterrence, punitive damages can be awarded only for conduct involving some element of outrage. *Hutchinson v. Luddy*, 582 Pa. 114, 870 A.2d 766 (2005). For that reason, Pennsylvania Supreme Court decisions establish that "punitive damages are an

‘extreme remedy’ available in only the most exceptional matters.” *Wagner v. Onofrey*, 2006 Pa. Dist. & Cnty. Dec. LEXIS 333, *11 (Pa. Com. Pl. 2006) (citing *Phillips v. Cricket Lighters*, 584 Pa. 179, 188, 883 A.2d 439, 445 (2005)). “In fact, punitive damages are specifically designed to heap an additional punishment on a defendant who is found to have acted in a fashion which is particularly egregious.” *Wagner* at *12.

92. Punitive damages may not be awarded for misconduct that constitutes ordinary negligence such as inadvertence, mistake and errors of judgment. *Martin v. Johns-Manville Corp.*, 494 A.2d 1088, 1097 (Pa. 1985); *McDaniel v. Merck, Sharp & Dohme*, 533 A.2d 436, 437 (Pa. Super. 1987). An award of punitive damages must be supported by evidence of conduct more serious than the mere commission of the underlying tort. *Allstate Ins. Co. v. A.M. Pugh Assoc., Inc.*, 604 F. Supp. 85, 99 (M.D. Pa. 1984).

93. Specifically, with regard to punitive damages in the context of claims against health care providers, the Medical Care and Reduction of Error (MCARE) Act permits punitive damages only to be awarded as follows:

(a) Award. -- Punitive damages may be awarded for conduct that is the result of the health care provider’s willful or wanton conduct or reckless indifference to the rights of others. In assessing punitive damages, the trier of fact can properly consider the character of the health care provider’s act, the nature and extent of the harm to the patient that the health care provider caused or intended to cause and the wealth of the health care provider.

(b) Gross Negligence. -- A showing of gross negligence is insufficient to support an award of punitive damages.

40 P.S. §1303.505.

94. The Supreme Court has made clear that when assessing the propriety of the imposition of punitive damages, “the state of mind of the actor is vital. The act or failure to act, must be intentional, reckless or malicious.” *Hutchinson, supra* at 770. An appreciation of the risk

is a necessary element of the mental state required for the imposition of punitive damages. *Id.* at 772.

95. Thus, “a punitive damages claim must be supported by evidence sufficient to establish that (1) a defendant had a subjective appreciation of the risk of harm to which the plaintiff was exposed and that (2) he acted, or failed to act, as the case may be, in conscious disregard of that risk.” *Id.*

96. Since professional negligence actions involve allegations that health care professionals deviated from the governing standard of care, punitive damages are generally not recoverable in malpractice actions unless the medical provider’s deviation from the applicable standard of care is so egregious as to evince a conscious or reckless disregard of a patent risk of harm to the patient. *Wagner, supra.*

97. Where the facts as averred show nothing more than negligence, a lapse in judgment, or mere inadvertence, courts in Pennsylvania have dismissed pleas and claims for punitive damages, often at the pleadings stage of litigation and even if the complaint alleged severe injuries or death. *See, e.g., Brownawell v. Bryan*, 40 Pa. D. & C.3d 604, 606 (Pa. Com. Pl. 1985) (dismissing punitive damages claim where a plaintiff alleged that a physician negligently performed a spinal fusion surgery that left the plaintiff with severe neurological defects, and noting that “**the mere pleading of outrageous conduct** does not, of course, satisfy the requirement stating facts which, if proven, would form a basis for a jury concluding that the conduct was such that an award of punitive damages was warranted.”) (emphasis added); *Wagner, supra* at *11 (contentions that physician failed to prescribe antibiotics, order certain tests or request an infectious disease consult constituted “nothing more than ordinary negligence and are insufficient to support an award of punitive damages.”); *McCardle v. Aldinger*, 5 Pa. D. & C.4th 421, 428 (Pa.

Com. Pl. 1996) (sustaining preliminary objections and dismissing claim for punitive damages where the plaintiff alleged negligence in the prenatal care of her child that led to the child was stillborn and holding that “[i]t is not the outcome of the alleged negligence that is of consideration, but rather the alleged conduct of defendants that is at issue.”); *Flurer v. Pocono Medical Ctr.*, 15 Pa. D. & C.4th 645, 670 (Pa. Com. Pl. 1992) (sustaining preliminary objections and finding that plaintiffs were not “capable of pleading the requisite behavior” for an award of punitive damages where a hospital allegedly failed to properly utilize a fetal monitor on a pregnant woman who was involved in a serious car accident and thereafter delivered a stillborn child).

98. Conversely, punitive damages have been reserved for those situations that are truly egregious and utterly outrageous, and typically involve aggravating or other factors that evince a particularly reckless mind or evil motive. *See, e.g., Medvecz v. Choi*, 569 F.2d 1221, 1227-30 (3rd Cir. 1987) (anesthesiologist who abandoned patient on operating room table and left room for a lunch break without securing a suitable replacement could be liable for punitive damages to patient who suffered irreversible paralysis from anesthesia complication that developed during his absence); *Hoffman v. Memorial Osteopathic Hospital*, 492 A.2d 1382, 386-87 (Pa. Super. 1985) (evidence that emergency room physician allowed Guillain-Barre Syndrome patient suffering from neurological paralysis to remain crying and immobile on floor for two hours as physician repeatedly stepped over patient was sufficient to support punitive damages claim); *Guernsey v. County Living Personal Care Home, Inc.*, 2006 U.S. Dist. LEXIS 31450, 2006 WL 1412765 (M.D. Pa. 2006) (punitive damages recoverable from nursing home officials who allowed resident to have access to room of 86-year old Alzheimer’s patient where he repeatedly raped her, since nursing home was aware of resident’s prior criminal convictions for sex registration as a sexual offender under Megan’s Law, and his prior instances of grabbing and kissing staff); *Lawrence v.*

Kunkle, 75 D. & C. 4th 370 (Pa. Com. Pl. 2005) (patient could maintain punitive damages claim against physician who refused to perform emergency surgery because patient did not have medical insurance even though physician knew that patient would likely suffer permanent neurologic and functional deficits if surgery was delayed).

99. The facts underlying Plaintiffs' bare assertions of reckless, outrageous or similar behavior do not even remotely meet the requisite standard under Pennsylvania law that would permit an award of punitive damages.

100. Pursuant to § 505(c) of the MCARE Act, punitive damages are specifically restricted in claims involving vicarious liability:

(c) Vicarious liability. -- Punitive damages shall not be awarded against a healthcare provider who is only vicariously liable for the actions of its agent that caused the injury unless it can be shown by a preponderance of the evidence that the party knew of and allowed the conduct of its agent that resulted in an award of punitive damages.

See 40 P.S. §1303.505(c).

101. Plaintiffs allege in this action that M.E. was fed cow's milk-based products while she was in the NICU at Pennsylvania Hospital, and that Moving Defendants "knew or should have known" that these products increased the risk of NEC. *See* Exhibit F, ¶ 13.

102. Even if such actions were claimed to be egregious or malicious such that punitive damages were permissible, which is denied for the reasons stated above, Plaintiffs must allege facts to establish that Moving Defendants had actual knowledge of the alleged wrongful conduct and nevertheless allowed it, but they have not done so. *See Zazzera v. Roche*, 54 D. & C. 4th 225, 238 (Pa. Com. Pl. 2001); *Dean Witter Reynolds, Inc. v. Genteel*, 499 A.2d 637 (Pa. Super. 1985).

103. In this matter, Plaintiffs have failed to plead any facts to suggest that Moving Defendants were aware of any alleged misconduct by any individual alleged to be an agent and allowed such conduct to continue.

104. For all these reasons, Plaintiffs' demand for punitive damages must be stricken with prejudice as to Moving Defendants, along with all allegations of reckless and similar conduct.

E. MOTION TO DISMISS, OR IN THE ALTERNATIVE STRIKE, PLAINTIFF-PARENT'S CLAIMS

- i. **Plaintiff-parent's claims should be dismissed for failure to articulate a cause of action, or alternatively, Plaintiff-parent's claims should be stricken for failure to comply with Pa.R.C.P. 1020(b).**

105. Plaintiff-parent seeks to recover damages in her own right and as the parent and natural guardian of M.E.

106. Plaintiffs' Second Amended Complaint includes allegations in each count against Moving Defendants that Plaintiff-parent "suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries." *See* Exhibit F, ¶¶ 166, 192.

107. However, no specific cause of action is asserted as to any damages sought by and on behalf of Plaintiff-parent, who is not alleged in the Second Amended Complaint to have suffered any physical injuries as a result of the alleged negligent conduct of Moving Defendants. For this reason, Plaintiff-parent's claim should be dismissed.

108. Further, even if Plaintiff-parent had properly articulated a cause of action in the Second Amended Complaint to allow her to recover damages in her own right, the Second Amended Complaint should be stricken pursuant to Pa.R.C.P. 1020(b), which provides as follows:

If persons join as plaintiffs under Rules 2228, 2229(a) or (e), the complaint shall state the cause of action, any special damage, and the demand for relief of each

plaintiff in a separate count, preceded by a heading naming the parties to the causes of action therein set forth.

109. Accordingly, it is improper for Plaintiffs to plead in a single count claims on behalf of both the Plaintiff-minor and the Plaintiff-parent, as was done in the Second Amended Complaint filed herein. Claims on behalf of each of the Plaintiffs must be set forth in separate counts of the Second Amended Complaint, specifically identifying the cause of action asserted and relief sought in each count.

ii. **Plaintiff-parent's claims should be dismissed because her claims are time-barred and she has not alleged sufficient facts to demonstrate that the limitations period should be tolled.**

110. Although the statute of limitations for claims asserted on behalf of minors are tolled until the age of majority, Plaintiff-parent's claims were not similarly tolled and were required to have been brought within two years of the alleged injury. *See Hathi v. Krewstown Park Apts*, 561 A.2d 1261 (Pa. Super. 1989); 42 Pa.C.S. § 5524.

111. Plaintiffs allege that M.E. was born on September 28, 2007, was fed the Defendant Manufacturers' products after her birth, and developed NEC thereafter. *See Exhibit F*, ¶¶ 11-20.

112. Thus, since Plaintiffs' original Complaint was filed on March 24, 2022, Plaintiff-parent's claims herein are clearly time-barred based on the applicable statute of limitations.

113. In an attempt to circumvent the statute of limitations issues for the Plaintiff-parent, Plaintiffs go to great lengths in their Second Amended Complaint to essentially assert that Plaintiff-parent's claims are somehow preserved by way of the discovery rule.

114. In particular, Plaintiffs allege that Plaintiff-parent did not discover a factual basis for Plaintiffs' negligence claims before the expiration of the limitations period, alleging that Moving Defendants "hid the cause" of M.E.'s NEC diagnosis and thus Plaintiff-parent had "no

reason to know or suspect” that the products at issue in this case allegedly caused M.E.’s NEC. See Exhibit F, ¶¶ 31-50.

115. The discovery rule, which is a narrow exception that extends the limitation period in certain limited circumstances, does not apply here.

116. The discovery rule provides that where the existence of the injury is not known to the complaining party and such knowledge cannot reasonably be ascertained within the prescribed period, the period of limitation does not begin to run until discovery of the injury is reasonably possible. *Hayward v. Medical Center of Beaver County*, 608 A.2d 1040, 1043 (Pa. 1992) (abrogated on other grounds).

117. Under the discovery rule, the statute of limitations is not triggered “until the plaintiff knows or reasonably should know (1) that he or she has been injured, and (2) that this injury has been caused by another party’s conduct.” See *Levenson v. Souser*, 557 A.2d 1081, 1086, 87 (Pa. Super. 1989).

118. The party asserting the discovery rule bears the burden of establishing that he or she falls within it. See *Cochran v. GAF Corp.*, 666 A.2d 245, 249 (Pa. 1995).

119. “[I]t is well-settled that the reasonable diligence standard is objective, as the question is not what the plaintiff actually knew of the injury or its cause, but what he might have known by exercising the diligence required by law.” *Nicolaou v. Martin*, 195 A.3d 880, 893 (Pa. 2018) (citations omitted).

120. Plaintiffs allege boilerplate accusations that Plaintiff-parent was unable to discover the cause of M.E.’s NEC diagnosis earlier, and therefore, the limitations period is tolled, because “Defendants hid the cause of NEC” from Plaintiff-parent and Defendants “fraudulently concealed” the risks of NEC from Defendant Manufacturer’s products. See Exhibit F, ¶¶ 31-50.

121. Plaintiffs do not allege *any* facts to support the claim that Moving Defendants “hid” information from Plaintiff-parent or “fraudulently concealed” any risks from her.

122. The fatal flaw underlying Plaintiffs’ discovery rule argument is that it presupposes that a risk existed, and Moving Defendants were aware of that risk.

123. However, Plaintiffs have not plead sufficient facts to support this claim, which is also belied by FDA regulations and other statutory frameworks that exist for the purpose of ensuring the safety of infant formula in the United States.

124. The FDA does not restrict the use of cow’s milk-based products for premature or low birth weight infants, and any of Plaintiffs’ allegations to the contrary are completely unsupported and baseless.

125. Based on the foregoing, Plaintiffs have failed to plead sufficient facts to demonstrate that the applicable limitations period should be tolled.

F. MOTION TO STRIKE PLAINTIFFS’ COMPLAINT FOR FAILURE TO COMPLY WITH P.A.R.C.P. 1024

126. Pennsylvania Rule of Civil Procedure 1024(a) requires verification of every pleading containing a factual averment based upon the signer’s personal knowledge or information and belief.

127. Rule 1024(c) requires that the verification be made by one or more of the parties filing the pleading.

128. In this case, no verification is attached to the Second Amended Complaint in violation of Rule 1024. *See* Exhibit F.

129. Accordingly, the Second Amended Complaint should be stricken for lack of an appropriate verification.

WHEREFORE, Defendants the Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital and the Trustees of the University of Pennsylvania d/b/a Penn Medicine respectfully request that this Honorable Court sustain the instant Preliminary Objections and enter the attached proposed Order.

Respectfully submitted:

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Dated: August 6, 2024

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 The Trustees of the University of
 Pennsylvania d/b/a Penn Medicine*

TERRAINE ABDULLAH, on her own behalf	:	COURT OF COMMON PLEAS
and as Parent and Natural Guardian of M.E., a	:	PHILADELPHIA COUNTY
Minor,	:	
Plaintiffs,	:	CIVIL ACTION
v.	:	
MEAD JOHNSON & COMPANY, LLC, et al.,	:	MARCH TERM 2022
Defendants.	:	NO. 2583

**MEMORANDUM OF LAW IN SUPPORT OF PRELIMINARY OBJECTIONS OF
 DEFENDANTS THE PENNSYLVANIA HOSPITAL OF THE UNIVERSITY OF
 PENNSYLVANIA HEALTH SYSTEM AND THE TRUSTEES OF THE UNIVERSITY
 OF PENNSYLVANIA TO PLAINTIFFS' SECOND AMENDED COMPLAINT**

Defendants The Pennsylvania Hospital of the University of Pennsylvania Health System (“Pennsylvania Hospital”) and The Trustees of the University of Pennsylvania (“Trustees”) (collectively, “Moving Defendants”), by and through counsel Burns White LLC, hereby file the within Preliminary Objections to Plaintiffs’ Second Amended Complaint, and in support thereof aver as follows:

I. MATTER BEFORE THE COURT

Preliminary Objections of Defendants The Pennsylvania Hospital of the University of Pennsylvania Health System (“Pennsylvania Hospital”) and The Trustees of the University of Pennsylvania to Plaintiffs’ Second Amended Complaint.

II. STATEMENT OF QUESTIONS PRESENTED

1. Whether this Honorable Court should dismiss Count VI of Plaintiffs' Amended Complaint with prejudice because Plaintiffs' Second Amended Complaint does not support the claim that cow's milk-based products are unreasonably dangerous?

Suggested answer in the affirmative.

2. Whether this Honorable Court should dismiss Count VI of Plaintiffs' Second Amended Complaint with prejudice because Moving Defendants cannot be held liable for negligent failure to warn on the basis that they are a supplier of such products?

Suggested answer in the affirmative.

3. Whether this Honorable Court should dismiss Count VI of Plaintiffs' Second Amended Complaint with prejudice because it improperly alleges that Moving Defendants were required to obtain Plaintiff-parent's informed consent to use of cow's milk-based products for feeding of Plaintiff-minor and warn her of the risks and/or alternatives of same?

Suggested answer in the affirmative.

4. Whether this Honorable Court should dismiss Count VII of Plaintiffs' Second Amended Complaint with prejudice because Moving Defendants cannot be held liable on a corporate negligence theory for a product which is regulated by the FDA and which is not precluded for use in premature or low birth weight infants, and where a hospital cannot be held liable for corporate negligence based on the alleged negligence of an individual health care provider?

Suggested answer in the affirmative.

5. Whether this Honorable Court should dismiss Count VII of Plaintiffs' Second Amended Complaint with prejudice as to the Trustees of the University of Pennsylvania since it is not a hospital and because corporate negligence duties are non-delegable?

Suggested answer in the affirmative.

6. Whether this Honorable Court should strike Plaintiffs' Second Amended Complaint in its entirety for insufficient specificity of the facts and alleged injuries?

Suggested answer in the affirmative.

7. Whether this Honorable Court should strike Plaintiffs' claims for punitive damages as to Moving Defendants because the Second Amended Complaint fails to plead facts providing a basis for an award of punitive damages?

Suggested answer in the affirmative.

8. Whether this Honorable Court should strike Plaintiff-parent's claims for failure to state a cause of action and for failure to plead separate causes of action pursuant to Pa.R.C.P. 1020?

Suggested answer in the affirmative.

9. Whether this Honorable Court should strike Plaintiff-parent's claims because they are time-barred and Plaintiff-parent has failed to allege sufficient facts to demonstrate that the limitations period should be tolled?

Suggested answer in the affirmative.

10. Whether this Honorable Court should strike Plaintiffs' Second Amended Complaint for lack of an appropriate verification?

Suggested answer in the affirmative.

III. INTRODUCTION AND FACTUAL BACKGROUND

Plaintiffs instituted this action via the filing of a Complaint on March 24, 2022 against Moving Defendants as well as Co-Defendants Mead Johnson & Company, LLC, Mead Johnson Nutritional Company (collectively referred to as “Mead Johnson”) and Abbott Laboratories (“Abbott”). A true and correct copy of Plaintiffs’ Complaint is attached hereto as Exhibit “A.”

On June 9, 2023, Moving Defendants filed preliminary objections to Plaintiffs’ Complaint, seeking the Court to: 1) dismiss Counts VI and VII for lack of specificity; 2) strike Plaintiffs’ Complaint in its entirety for insufficient specificity of the facts and alleged injuries; 3) strike Plaintiffs’ claims for punitive damages for failure to plead sufficient facts; and 4) strike Plaintiff-parent’s claims for failure to state a cause of action, for failure to plead separate causes of action, and based on the applicable statute of limitations. A true and correct copy of Preliminary Objections to Plaintiffs’ Complaint is attached hereto as Exhibit “B.”

On September 8, 2023, Plaintiffs filed an Amended Complaint, which still contained substantially all of the fatal flaws that Moving Defendants raised in their first set of Preliminary Objections. A true and correct copy of Plaintiffs’ Amended Complaint is attached hereto as Exhibit “C.” Thus, on September 27, 2023, Moving Defendants filed Preliminary Objections to Plaintiffs’ Amended Complaint. A true and correct copy of Moving Defendants’ Preliminary Objections to Plaintiffs’ Amended Complaint is attached hereto as Exhibit “D.” On March 20, 2024, the Court sustained Moving Defendants’ preliminary objections, and ordered Plaintiffs to file an Amended Complaint “setting forth their claims for professional negligence and damages with specificity.” A true and correct copy of the Court’s Order is attached hereto Exhibit “E.”

On July 17, 2024, Plaintiffs filed a Second Amended Complaint, which includes some additional factual allegations, but the same fatal flaws are still present. A true and correct copy of Plaintiffs' Second Amended Complaint is attached hereto as Exhibit "F."

Plaintiffs have filed a slew of essentially identical lawsuits against Pennsylvania Hospital and other hospitals in Philadelphia based on claims relating to alleged ingestion of cow's milk-based infant formula by premature infants following their birth.⁴ Plaintiffs allege that the Plaintiff-minor, M.E., was diagnosed with necrotizing enterocolitis (NEC), a gastrointestinal disorder that premature infants are at increased risk to develop. *See* Exhibit F, ¶¶ 16, 22. Plaintiffs allege that premature infants fed with their mother's breast milk or donor breast milk are at decreased risk of developing NEC as compared with infants given cow's milk-based infant formula and fortifiers added to human milk.⁵ In addition to asserting product liability claims against the infant formula manufacturers Mead Johnson and Abbott, Plaintiffs have alleged that Moving Defendants are liable based on theories of failure to warn and corporate liability.⁶ Plaintiffs aver that M.E. was born prematurely on September 28, 2007 and that "upon information and belief" she "was fed Similac and/or Enfamil cow's milk-based products by staff at Pennsylvania Hospital after his

⁴ Lawsuits involving identical claims have been filed against the Hospital of the University of Pennsylvania, Temple University Hospital, Albert Einstein Medical Center, Jefferson Abington Hospital and Thomas Jefferson University Hospital.

⁵ Although Plaintiffs aver in the Second Amended Complaint that NEC is caused by cow's milk-based infant formula and fortifiers, as discussed *infra* and in the accompanying Memorandum of Law, Plaintiffs do not cite any study or statement in the Second Amended Complaint that indicates NEC is caused by cow's milk-based products.

⁶ As is discussed below, infant formulas are regulated by the United States Food and Drug Administration and are required to include specified vitamins and nutrients, including infant formulas intended for low birth weight infants. The FDA does not restrict the use of cow's milk-based infant formula for premature or low birth weight infants. Plaintiff's contention that cow's milk-based infant formula should never be given to premature infants is not supported by the FDA.

birth.” *Id.*, ¶¶ 11-12. Plaintiffs allege that “[u]pon information and belief, M.E. developed NEC after ingesting Defendant Manufacturers’ products.” *Id.*, ¶ 13.

Plaintiffs aver that beginning on September 29, 2007, M.E. was fed with mother’s breast milk which was fortified with bovine-based human milk fortifier which “upon information and belief was manufactured by” Defendant Abbott Laboratories and/or Defendant Mead Johnson. *Id.*, ¶ 14. Plaintiffs further aver that “no later than October 29, 2007,” Dr. Thomas Mollen “revised his nutritional orders” to start feeding M.E. Defendant Abbott’s “‘Special Care’ bovine based formula which M.E. was ultimately fed for a total of 31 days while under the care of Pennsylvania Hospital.” *Id.*, ¶ 15. According to Plaintiffs, M.E. was diagnosed with stage II-B Medical NEC on November 2, 2007, and was subsequently transferred to Children’s Hospital of Philadelphia, where M.E. received treatment from November 2 to November 8, 2007. *Id.*, ¶ 16. Plaintiff allege that M.E. was discharged from CHOP on November 8, 2007 and returned to Pennsylvania Hospital, where M.E. was given two different products manufactured by Abbott until M.E. was discharged on December 5, 2007. *Id.*, ¶¶ 17, 19. Plaintiffs generally allege that “[a]s a result of the Stage II-B Medical NEC diagnosis,” M.E. “experienced developmental delay, including but not limited to neurodevelopmental impairment.” *Id.*, ¶ 20.

Moving Defendants Preliminarily Object to Plaintiffs’ Second Amended Complaint for the reasons stated below and as set forth in the accompanying Memorandum of Law, which is incorporated herein by reference.

IV. ARGUMENT

A. DEMURRER TO COUNT VI: FAILURE TO WARN

Pursuant to Pa.R.C.P. 1028(a)(4), a party may file preliminary objections to a complaint, in the nature of a demurrer, for legal insufficiency in a pleading. A court should grant a demurrer

where, accepting as true all well pled facts, a legal cause of action cannot be maintained upon those facts. Pa.R.C.P. 1028(a)(4); *See also, Willet v. Pennsylvania Med. Catastrophe Loss Fund*, 702 A.2d 850, 853 (Pa. 1997).

In alleging a failure to warn claim against Moving Defendants, Plaintiffs appear to conflate a cause of action for negligent failure to warn, with a cause of action for failing to obtain informed consent. Under either theory, Count VI is legally deficient and must be dismissed.

- i. **Plaintiffs failed to state a cause of action for negligent failure to warn because Plaintiffs' baseless assertions that Moving Defendants are "suppliers" and that the cow's milk-based products at issue were unreasonably dangerous, are not support with sufficient factual allegations.**

Plaintiffs allege in Count VI of the Second Amended Complaint that Moving Defendants "as purchaser, supplier, and/or distributor of the products at issue in the litigation" owed Plaintiffs and the public a duty to provide products that were free of unreasonable risk of harm. *See Exhibit F, ¶ 154.* Taking the facts as pleaded by Plaintiffs as true, Plaintiffs have failed to state a claim for negligent failure to warn against Moving Defendants because they have failed to plead sufficient facts to support any assertion that Moving Defendants are "suppliers" and that the products at issue were "unreasonably dangerous."

Pennsylvania courts have adopted Restatement (Second) of Torts § 388 in cases involving a claim of negligent failure to warn." *Dauphin Deposit Bank & Trust Co. v. Toyota Motor Corp.*, 596 A.2d 845, 850 (Pa. Super. 1991). Section 388 governs this cause of action, and provides:

One who supplies directly or through a third person a chattel for another to use is subject to liability to those whom the supplier should expect to use the chattel with the consent of the other or to be endangered by its probable use, for physical harm caused by the use of the chattel in the manner for which and by a person for whose use it is supplied, if the supplier

- (d) knows or has reason to know that the chattel is or is likely to be dangerous for the use for which it is supplied, and

- (e) has no reason to believe that those for whose use the chattel is supplied will realize its dangerous condition, and
- (f) fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be dangerous.

First, Moving Defendants had no duty to warn of the nature of cow's milk-based products under § 388 because medical providers are not "supplying" a product to a patient within the stream of commerce. Thus, Count VI should be dismissed for this reason alone.

Additionally, Plaintiffs must aver sufficient facts demonstrating the Defendant Manufacturers' products are unreasonably dangerous for their intended use, triggering Moving Defendants' duty to warn, which Plaintiffs have failed to do. "The threshold inquiry in all products liability cases is whether there is a defect which rendered the product unreasonably dangerous." *Weiner v. American Honda Motor Co., Inc.*, 718 A.2d 305, 307 (Pa. Super. 1998). "A product is defective when it is not safe for its intended use, i.e., the product left the supplier's control lacking any element necessary to make it safe for its intended use." *Id.* at 308.

At the outset of their Second Amended Complaint, Plaintiffs appropriately acknowledge that "[p]reterm and low-birth-weight infants are *especially susceptible to NEC*." See Exhibit F, ¶ 22 (emphasis added). Following this, Plaintiffs make the core claim of their Second Amended Complaint – that cow's milk-based feeding products cause NEC in preterm and low birth weight infants – and that "[e]xtensive scientific research, including numerous randomized controlled trials" confirm this claim. See *id.* However, Plaintiffs do not allege any facts to support their claim that "scientific evidence" demonstrates that cow's milk-based feeding products cause NEC in preterm and low birth weight infant.

Plaintiffs appear to base this core claim on flawed studies cited in the original Complaint that Plaintiffs subsequently omitted in their Amended Complaint and Second Amended Complaint.

In their original Complaint, in support of their assertion that the products at issue were dangerous to M.E., Plaintiffs referenced five studies comparing cow's milk-based products to breast milk, a Surgeon General report on the subject, and a statement by the American Academy of Pediatrics. *See* Exhibit A, ¶¶ 17-22. As Moving Defendants argued in their Preliminary Objections to Plaintiffs' original Complaint, the studies cited by Plaintiffs demonstrate only, assuming the facts as true as stated by Plaintiffs, that premature infants are at high risk of NEC, and that feeding such infants with breast milk may be better at reducing the risk of NEC than cow's milk-based alternatives. *See* Exhibit A, ¶¶ 17-22. Plaintiffs appear to concede that the aforementioned studies did not support their allegations because Plaintiffs removed all references to the studies and deleted paragraphs 17 through 22 in their Amended Complaint, and again in their Second Amended Complaint.

In lieu of relying on the studies originally cited by Plaintiffs in their Complaint, Plaintiffs generally allege in their Second Amended Complaint that "scientific evidence" exists demonstrating that cow's milk-based products cause NEC. *See, e.g.*, Exhibit F, ¶¶ 27-30. However, Plaintiffs do not plead any additional facts to support their assertion that such "scientific evidence" exists.

Further, Plaintiffs' baseless assertion that the cow's milk-based products at issue were "unreasonably dangerous" is incompatible with the reality that such products are carefully regulated by the United States Food and Drug Administration ("FDA"), and Plaintiffs are not alleging that Moving Defendants did anything contrary to the applicable federal regulations. The Infant Formula Act of 1980 ("IFA") was enacted "to assure the safety and nutrition of infant formulas." *See* Pub. L. No. 96-359, 94 Stat. 1190. The IFA and its implementing regulations outline the requirements that infant formula must meet, including how infant formula is made, its contents

and ingredients, and the labels used on its packages. *See* 21 U.S.C. § 350a; 21 C.F.R. §§ 106-07. Neither the IFA nor the regulations exclude cow’s milk as an ingredient, and many infant formulas for sale include cow’s milk. 21 C.F.R. § 106.3 (“infant formula” is a “food for infants by reason of its *simulation* of human milk”) (emphasis added). 21 U.S.C. § 350a; 21 C.F.R. §§ 107.50. Plaintiffs have not alleged any facts that would justify overlooking an entire regulatory framework dedicated to ensuring the safety of infant formula in the United States.

Thus, Plaintiffs have failed to state a claim for negligent failure to warn against Moving Defendants as they have failed to state facts to establish that cow’s milk-based products is unreasonably dangerous for its intended purpose. Alternatively, even if the products at issue here can be viewed as unreasonably dangerous, Plaintiffs still have failed to plead sufficient facts that Moving Defendants are a supplier of products that are ancillary to the medical services provided to Plaintiffs.

ii. **Count VI is also deficient to the extent Plaintiffs’ “failure to warn” claim is based on an alleged failure to obtain informed consent.**

Plaintiffs’ failure to warn claim is similarly precluded to the extent that Plaintiffs are alleging that Defendants, in providing medical care to Plaintiff-minor, failed to obtain Plaintiff-parent’s consent to the use of cow’s milk-based products and failed to warn of the purported risks and alternatives of such products. Plaintiffs are impliedly asserting that Moving Defendants failed to obtain Plaintiff-parent’s informed consent as to whether she should use cow’s milk-based products to feed her child, based on the alleged risks of cow’s milk-based products. However, such a claim is not cognizable under Pennsylvania law.

Claims for informed consent in medical malpractice actions are governed by the Medical Care Availability and Reduction of Error Act, which provides as follows:

(a) **Duty of Physicians.**--Except in emergencies, a physician owes a duty to a patient to obtain the informed consent of the patient or the patient's authorized representative prior to conducting the following procedures:

(1) Performing surgery, including the related administration of anesthesia.

(2) Administering radiation or chemotherapy.

(3) Administering a blood transfusion.

(4) Inserting a surgical device or appliance.

(5) Administering an experimental medication, using an experimental device or using an approved medication or device in an experimental manner.

(b) Description of procedure.--Consent is informed if the patient has been given a description of a procedure set forth in subsection (a) and the risks and alternatives that a reasonably prudent patient would require to make an informed decision as to that procedure. The physician shall be entitled to present evidence of the description of that procedure and those risks and alternatives that a physician acting in accordance with accepted standards of medical practice would provide.

40 P.S. §1303.504 (emphasis added).

The language of the statute above reveals two significant tenets. The first is that the informed consent statute does not apply to the use of cow's milk-based products in feeding premature infants, since feeding is not a "procedure." Informed consent has not been extended to any type of therapeutic treatment involving an ingestible therapeutic drug, which the court defined as "an ongoing treatment upon examination by the treating physician, where any change of condition can be diagnosed and controlled." *Boyer v. Smith*, 497 A.2d 646, 648 (Pa. Super. 1985). The Superior Court ruled that the informed consent doctrine is premised upon the legal theory that the performance of a medical procedure without a patient's informed consent constitutes a technical assault or battery, and that merely prescribing an oral medication, which does not involve touching,

does not amount to battery and therefore, obtaining informed consent is not required under those circumstances. *Id.* at 649.

The same principles clearly apply to infant feeding because, just like when a provider administers medication, the provider is not engaged in “touching” when formula or human milk fortifiers are ordered for an infant’s feeding. Thus, there is no basis for Plaintiffs to contend that Plaintiff-parent’s consent was required for the use of cow’s milk-based products to feed her infant, including warning her of the risks or alternatives of same.

Second, the informed consent statute only applies to physicians, not hospitals, in the context of medical procedures. *See* 40 P.S. § 1303.504; *see also Valles v. Albert Einstein Medical Center*, 805 A.2d 1232, 1239 (Pa. 2002) (holding that duty to obtain informed consent belongs “solely to the physician” and thus a medical facility cannot be vicariously liable for a failure to obtain informed consent); *Isaac v. Jameson Mem. Hosp.*, 932 A.2d 924, 930 (Pa. Super. 2007) (“Given the unique nature of the doctrine and its origins as a technical battery, hospitals cannot be held vicariously liable for a physician’s failure to obtain informed consent because ‘a medical facility cannot maintain control over this aspect of the physician-patient relationship.’”); *Kelly v. Methodist Hosp.*, 664 A.2d 148 (Pa. Super. 1995) (holding that generally only the physician who performs the operation on the patient has the duty of obtaining his consent for the procedure).

For these reasons, Moving Defendants cannot be held liable for a physician’s failure to obtain proper informed consent, nor can they be liable for any alleged failure to obtain informed consent related to infant feeding, which is not a “procedure” under 40 P.S. § 1303.504. Accordingly, it is respectfully requested this Court sustain Moving Defendants’ Preliminary Objections to Count VI.

B. DEMURRER TO COUNT VII: CORPORATE LIABILITY OF HEALTH CARE PROVIDER

- i. **Moving Defendants cannot be held liable under a theory of corporate liability for failing to prevent the use of cow's milk-based products, which is regulated by the FDA and not precluded for use in premature or low birth weight infants.**

In *Thompson v. Nason Hospital*, 591 A.2d 703, 708 (Pa. 1991), the Pennsylvania Supreme Court recognized the doctrine of corporate liability, holding that a hospital may be found directly liable for negligence if it fails to meet *any* of the following four duties: (1) a duty to use reasonable care in the maintenance of safe and adequate facilities and equipment; (2) a duty to select and retain only competent physicians; (3) a duty to oversee all persons who practice medicine within its walls as to patient care; and (4) a duty to formulate, adopt and enforce adequate rules and policies to ensure quality care for patients.

Plaintiffs' corporate liability claim fails based on the same rationale as the claim for failure to warn, since both claims are based on the alleged failure to provide warnings to patients related to the use of cow's milk-based products. Infant formula is regulated by the FDA, and there is no legal restriction on the use of cow's milk-based products for feeding of premature infants, as discussed *supra*. Indeed, the Infant Formula Act expressly acknowledges that it is permissible to provide cow's-milk based products to low birth weight infants. Further, as discussed above, Plaintiffs cannot demonstrate that cow's milk-based formula and fortifiers are unreasonably dangerous products.

Thus, there is no legal basis to contend that Moving Defendants can be held liable pursuant to a theory of corporate liability for failing to prevent the use of cow's milk-based products in the feeding of premature infants in the hospital.

ii. **Plaintiffs have not sufficiently pled facts to establish “systemic negligence” as required to bring a claim for corporate negligence.**

Courts considering the application of the duties set forth in *Thompson* have insisted on more than a simple finding of a negligent act by someone for whom the hospital is purportedly responsible. *Edwards v. Brandywine Hospital*, 652 A.2d 1382 (Pa. Super. 1995). In considering whether the plaintiff could sustain corporate negligence claims based on these allegations, the *Edwards* court analyzed the *Thompson* decision and delineated the standards required to sustain such a claim:

The *Thompson* theory of corporate liability **will not be triggered every time something goes wrong in a hospital which harms a patient . . .** To establish corporate negligence, a plaintiff must show more than an act of negligence by an individual for whom the hospital is responsible. Rather, *Thompson* requires a plaintiff to show that the hospital itself is breaching a duty and is somehow substandard...*Thompson* contemplates a kind of ‘**systemic negligence**’...

Id. at 1386-87 (citations omitted and emphasis added).

Corporate liability requires “more than individual acts of negligence.” *Id.* As noted by the court in *Edwards*, this reading of the Court’s opinion in *Thompson* is the only way to logically construe its holding, as hospitals are already held vicariously liable for the negligent acts of their employees and ostensible agents, while “*Thompson* requires a plaintiff to show that the **hospital itself** is breaching a duty and is somehow substandard.” *Id.* at 1387; *see also MacDonald v. Chestnut Hill Hosp.*, 2005 Phila. Ct. Com. Pl. LEXIS 273, 18 (Pa. C.P. 2005) (granting nonsuit to the hospital defendant where “[t]here was no evidence that protocols were routinely ignored to the detriment of patients or that the kind of systematic negligence on the part of CHH required by the *Edwards* decision was present.”)

Thus, a hospital may not be held liable via corporate negligence simply based on the alleged negligence of an individual health care provider. Accordingly, even if Plaintiffs could establish that

the use of cow's milk-based products was a breach of the standard of care by unidentified health care providers based on the specific circumstances of the Plaintiff-minor's case herein, which has not been pleaded by Plaintiffs considering the paucity of the allegations in the Second Amended Complaint, such evidence cannot support a finding of corporate liability. For the reasons stated above, Count VII of Plaintiffs' Second Amended Complaint should be dismissed with prejudice.

iii. **Plaintiffs are precluded from bringing a corporate negligence claim against Defendant Trustees of the University of Pennsylvania, which is merely a non-hospital, corporate parent of Pennsylvania Hospital.**

Even assuming Plaintiffs had a viable corporate negligence claim against Pennsylvania Hospital, any such claim is precluded against the Trustees of the University of Pennsylvania since it is not a hospital.

The *Thompson* holding has been extended to HMOs and nursing home facilities, where it was determined that such entities performed similar functions as hospitals. *See Shannon v. Health America Pennsylvania, Inc.*, 718 A.2d 828 (Pa. Super. 1998); *Scampone v. Highland Park Care Center, LLC*, 57 A.3d 582 (Pa. 2012). However, courts have routinely refused to extend the *Thompson* holding past such institutions to cover other entities, such as medical clinics and physician practice groups. *See Sutherland v. Monongahela Valley Hospital*, 856 A.2d 55, 62 (Pa. Super. 2004); *Dowhouer v. Judson*, 45 Pa. D. & C.4th 172, 180 (Pa.Com.Pl. 2000); *Brewer v. Geisinger Clinic, Inc.*, 45 Pa. D. & C.4th 215, 223 (Pa.Com.Pl. 2000); *Dibble v. Penn State Geisinger Clinic, Inc.*, 42 Pa. D. & C.4th 225 (Pa.Com.Pl. 1999); *Davis v. Gish*, 5 Pa. D. & C.5th 154, 159 (Pa.Com.Pl. 2007).

There is no legal basis for holding that the purported corporate parent of a hospital, such as the Trustees of the University of Pennsylvania, can be held liable under a theory of corporate negligence. Indeed, the *Scampone* Court cautioned that the trial court should ensure that “multiple

entities are not exposed to liability for breach of the same non-delegable duties.” 57 A.2d at 606-07. Thus, the corporate negligence count against Trustees must be dismissed as a matter of law.

C. MOTION TO STRIKE PLAINTIFFS’ SECOND AMENDED COMPLAINT FOR INSUFFICIENT SPECIFICITY AS TO THE FACTS AND ALLEGED INJURIES

Pursuant to Pa.R.C.P. 1028(a)(3), a party may file preliminary objections in the nature of a motion to strike for insufficient specificity in a pleading. A plaintiff’s Complaint is required to provide a defendant with notice of what the plaintiff’s claims are and the grounds upon which they rest, and the complaint must also formulate the issues by summarizing the facts essential to support the claims. *Alpha Tau Omega Fraternity v. The University of Pennsylvania*, 464 A.2d 1349, 1352 (Pa. Super. 1983) (*citations omitted*).

Pennsylvania Rule of Civil Procedure 1019(a) provides that “the material facts on which a cause of action or defense is based shall be stated in a concise and summary form.” Pa.R.C.P. 1019(a). As the Superior Court has noted,

Rule 1019(a) requires fact pleading. The purpose of 1019(a) is to require the pleader to disclose the material facts sufficient to enable the adverse party to prepare his case. A complaint therefore must do more than give the defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests. It should formulate the issues by fully summarizing the material facts. Material facts are ultimate facts, i.e., those facts essential to support the claim. Evidence from which such facts may be inferred not only need not but should not be alleged. Allegations will withstand challenge under 1019(a) if (1) they contain averments of all of the facts a plaintiff will eventually have to prove in order to recover, and (2) they are sufficiently specific so as to enable defendant to prepare his defense.

Baker v. Rangos, 324 A.2d 498, 505-506 (Pa. Super. 1974) (*citations and internal quotations omitted*)(emphasis added).

Further, it is well established that, with regard to the description of injuries sustained by a plaintiff, the Complaint must be stated with sufficient particularity to put the defendant on notice

of evidence that may be produced at trial. *Kelly v. Martino*, 99 A.2d 901 (Pa. 1953). **A plaintiff's Complaint must set forth the extent, nature, location and duration of the injuries suffered, and injuries that are permanent should be stated specifically.** *Miller v. Perrige*, 71 Pa. D. & C.2d 476, 479–80 (Pa. Com. Pl. 1975). *See, also, Kopan v. Hawk*, 14 Pa. D. & C.2d 713, 714 (Pa. Com. Pl. 1958) (“A catchall averment of “other injuries” is nothing more than a generalized averment under which any injuries whatever could be proved at the trial. Defendant would have no knowledge in advance of the trial of what they are.”)

Plaintiffs' Second Amended Complaint is deficient with regard to the specificity of the allegations of the relevant facts and injuries at issue in this case. Of the 193 paragraphs in Plaintiffs' Second Amended Complaint, only ten paragraphs address material facts relating to the Plaintiff-minor's care and treatment, diagnosis and injuries, which are utterly insufficient to enable Moving Defendants to prepare their defenses. *See* Exhibit F, ¶¶ 11-20. Plaintiffs' allegation that “upon information and belief,” the Plaintiff-minor was fed Similac *and/or* Enfamil after her birth (*Id.* at ¶ 13) does not comply with the fact-pleading requirements of Rule 1019(a), since such allegations do not provide Moving Defendants with appropriate notice of the facts as to whether and when the Plaintiff-minor actually ingested those cow's milk-based products. Additionally, Plaintiffs do not allege any factual basis to support their theory that cow's milk-based products caused M.E.'s NEC diagnosis, other than vague references to unidentified “scientific evidence.”

Plaintiffs also fail to state sufficient facts concerning the nature of the injuries and the “developmental delay” that are alleged to have resulted from the diagnosis of NEC. Further, Plaintiffs fail to allege any factual basis to support a causal connection between the NEC and M.E.'s alleged developmental delay. Plaintiffs' damages claim is not stated with particularity, is amorphous, vague, and open-ended. Pursuant to Pennsylvania pleading requirements, Moving

Defendants should not be compelled to defend a claim for which the statement of injury is unspecified and subject to change. These omissions are fatal defects. Therefore, Plaintiffs' Second Amended Complaint should be stricken in its entirety.

D. MOTION TO STRIKE PLAINTIFFS' CLAIMS FOR PUNITIVE DAMAGES

In the *Ad Damnum* clauses of Counts VI and VII of the Second Amended Complaint, Plaintiffs make baseless accusations that Moving Defendants engaged in outrageous, oppressive, reckless, malicious and/or fraudulent conduct that allegedly justify an award of punitive damages. However, Second Amended Complaint contains no specific allegations of conduct that would permit recovery of punitive damages as to Moving Defendants. Rather, Plaintiffs merely allege that "upon information and belief" M.E. may have been given a cow's milk-based product following birth, absent any context to indicate that such an action was inappropriate based on the specific issues involved in M.E.'s medical care and condition following birth. For example, the Second Amended Complaint does not give any indication whether Plaintiff-parent refused or was unable to provide breast milk and provides no information as to discussions between her and any health care providers regarding the purported use of cow's milk-based products.

Plaintiff's allegations of oppressive, outrageous, malicious and similar conduct must be rejected as mere boilerplate. As discussed above, the FDA specifically approves the use of infant formula in care of low birth weight infants, with no restriction as to the use of cow's milk-based products for such infants. Indeed, the fact that Plaintiffs have filed numerous lawsuits against at least five hospitals in Philadelphia based on identical claims belies the contention that Moving Defendants engaged in outrageous or malicious conduct in allegedly feeding the Plaintiff-minor with cow's milk-based products. Absent specific factual allegations to justify the claim that the use of cow's milk-based products in M.E.'s case was extreme and outrageous, there is no basis for

an award of punitive damages in this case. Merely contending that punitive damages should be awarded with no supporting factual justification requires dismissal of the claim.

Since the purpose of punitive damages is not compensation of a plaintiff but punishment of the defendant and deterrence, punitive damages can be awarded only for conduct involving some element of outrage. *Hutchinson v. Luddy*, 582 Pa. 114, 870 A.2d 766 (2005). For that reason, Pennsylvania Supreme Court decisions establish that “punitive damages are an ‘extreme remedy’ available in only the most exceptional matters.” *Wagner v. Onofrey*, 2006 Pa. Dist. & Cnty. Dec. LEXIS 333, *11 (Pa. Com. Pl. 2006) (citing *Phillips v. Cricket Lighters*, 584 Pa. 179, 188, 883 A.2d 439, 445 (2005)). “In fact, punitive damages are specifically designed to heap an additional punishment on a defendant who is found to have acted in a fashion which is particularly egregious.” *Wagner* at *12.

Punitive damages may not be awarded for misconduct that constitutes ordinary negligence such as inadvertence, mistake and errors of judgment. *Martin v. Johns-Manville Corp.*, 494 A.2d 1088, 1097 (Pa. 1985); *McDaniel v. Merck, Sharp & Dohme*, 533 A.2d 436, 437 (Pa. Super. 1987). An award of punitive damages must be supported by evidence of conduct more serious than the mere commission of the underlying tort. *Allstate Ins. Co. v. A.M. Pugh Assoc., Inc.*, 604 F. Supp. 85, 99 (M.D. Pa. 1984). Specifically, with regard to punitive damages in the context of claims against health care providers, the Medical Care and Reduction of Error (MCARE) Act permits punitive damages only to be awarded as follows:

- (a) Award. -- Punitive damages may be awarded for conduct that is the result of the health care provider’s willful or wanton conduct or reckless indifference to the rights of others. In assessing punitive damages, the trier of fact can properly consider the character of the health care provider’s act, the nature and extent of the harm to the patient that the health care provider caused or intended to cause and the wealth of the health care provider.

(b) Gross Negligence. -- A showing of gross negligence is insufficient to support an award of punitive damages.

41 P.S. §1303.505.

The Supreme Court has made clear that when assessing the propriety of the imposition of punitive damages, “the state of mind of the actor is vital. The act or failure to act, must be intentional, reckless or malicious.” *Hutchinson, supra* at 770. An appreciation of the risk is a necessary element of the mental state required for the imposition of punitive damages. *Id.* at 772. Thus, “a punitive damages claim must be supported by evidence sufficient to establish that (1) a defendant had a subjective appreciation of the risk of harm to which the plaintiff was exposed and that (2) he acted, or failed to act, as the case may be, in conscious disregard of that risk.” *Id.*

Since professional negligence actions involve allegations that health care professionals deviated from the governing standard of care, punitive damages are generally not recoverable in malpractice actions unless the medical provider’s deviation from the applicable standard of care is so egregious as to evince a conscious or reckless disregard of a patent risk of harm to the patient. *Wagner, supra*.

Where the facts as averred show nothing more than negligence, a lapse in judgment, or mere inadvertence, courts in Pennsylvania have dismissed pleas and claims for punitive damages, often at the pleadings stage of litigation and even if the complaint alleged severe injuries or death. *See, e.g., Brownawell v. Bryan*, 40 Pa. D. & C.3d 604, 606 (Pa. Com. Pl. 1985) (dismissing punitive damages claim where a plaintiff alleged that a physician negligently performed a spinal fusion surgery that left the plaintiff with severe neurological defects, and noting that “**the mere pleading of outrageous conduct** does not, of course, satisfy the requirement stating facts which, if proven, would form a basis for a jury concluding that the conduct was such that an award of punitive damages was warranted.”) (emphasis added); *Wagner, supra* at *11 (contentions that physician

failed to prescribe antibiotics, order certain tests or request an infectious disease consult constituted “nothing more than ordinary negligence and are insufficient to support an award of punitive damages.”); *McCardle v. Aldinger*, 5 Pa. D. & C.4th 421, 428 (Pa. Com. Pl. 1996) (sustaining preliminary objections and dismissing claim for punitive damages where the plaintiff alleged negligence in the prenatal care of her child that led to the child was stillborn and holding that “[i]t is not the outcome of the alleged negligence that is of consideration, but rather the alleged conduct of defendants that is at issue.”); *Flurer v. Pocono Medical Ctr.*, 15 Pa. D. & C.4th 645, 670 (Pa. Com. Pl. 1992) (sustaining preliminary objections and finding that plaintiffs were not “capable of pleading the requisite behavior” for an award of punitive damages where a hospital allegedly failed to properly utilize a fetal monitor on a pregnant woman who was involved in a serious car accident and thereafter delivered a stillborn child).

Conversely, punitive damages have been reserved for those situations that are truly egregious and utterly outrageous, and typically involve aggravating or other factors that evince a particularly reckless mind or evil motive. *See, e.g., Medvez v. Choi*, 569 F.2d 1221, 1227-30 (3rd Cir. 1987) (anesthesiologist who abandoned patient on operating room table and left room for a lunch break without securing a suitable replacement could be liable for punitive damages to patient who suffered irreversible paralysis from anesthesia complication that developed during his absence); *Hoffman v. Memorial Osteopathic Hospital*, 492 A.2d 1382, 386-87 (Pa. Super. 1985) (evidence that emergency room physician allowed Guillain-Barre Syndrome patient suffering from neurological paralysis to remain crying and immobile on floor for two hours as physician repeatedly stepped over patient was sufficient to support punitive damages claim); *Guernsey v. County Living Personal Care Home, Inc.*, 2006 U.S. Dist. LEXIS 31450, 2006 WL 1412765 (M.D. Pa. 2006) (punitive damages recoverable from nursing home officials who allowed resident to

have access to room of 86-year old Alzheimer's patient where he repeatedly raped her, since nursing home was aware of resident's prior criminal convictions for sex registration as a sexual offender under Megan's Law, and his prior instances of grabbing and kissing staff); *Lawrence v. Kunkle*, 75 D. & C. 4th 370 (Pa. Com. Pl. 2005) (patient could maintain punitive damages claim against physician who refused to perform emergency surgery because patient did not have medical insurance even though physician knew that patient would likely suffer permanent neurologic and functional deficits if surgery was delayed).

The facts underlying Plaintiffs' bare assertions of reckless, outrageous or similar behavior do not even remotely meet the requisite standard under Pennsylvania law that would permit an award of punitive damages. Pursuant to § 505(c) of the MCARE Act, punitive damages are specifically restricted in claims involving vicarious liability:

(c) Vicarious liability. -- Punitive damages shall not be awarded against a healthcare provider who is only vicariously liable for the actions of its agent that caused the injury unless it can be shown by a preponderance of the evidence that the party knew of and allowed the conduct of its agent that resulted in an award of punitive damages.

See 40 P.S. §1303.505(c).

Plaintiffs allege in this action that M.E. was fed cow's milk-based products while she was in the NICU at Pennsylvania Hospital, and that Moving Defendants "knew or should have known" that these products increased the risk of NEC. *See* Exhibit F, ¶ 13. Even if such actions were claimed to be egregious or malicious such that punitive damages were permissible, which is denied for the reasons stated above, Plaintiffs must allege facts to establish that Moving Defendants had actual knowledge of the alleged wrongful conduct and nevertheless allowed it, but they have not done so. *See Zazzera v. Roche*, 54 D. & C. 4th 225, 238 (Pa. Com. Pl. 2001); *Dean Witter Reynolds, Inc. v. Genteel*, 499 A.2d 637 (Pa. Super. 1985).

In this matter, Plaintiffs have failed to plead any facts to suggest that Moving Defendants were aware of any alleged misconduct by any individual alleged to be an agent and allowed such conduct to continue. For all these reasons, Plaintiffs' demand for punitive damages must be stricken with prejudice as to Moving Defendants, along with all allegations of reckless and similar conduct.

E. MOTION TO DISMISS, OR IN THE ALTERNATIVE STRIKE, PLAINTIFF-PARENT'S CLAIMS

- i. **Plaintiff-parent's claims should be dismissed for failure to articulate a cause of action, or alternatively, Plaintiff-parent's claims should be stricken for failure to comply with Pa.R.C.P. 1020(b).**

Plaintiff-parent seeks to recover damages in her own right and as the parent and natural guardian of M.E. Plaintiffs' Second Amended Complaint includes allegations in each count against Moving Defendants that Plaintiff-parent "suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries." See Exhibit F, ¶¶ 166, 192. However, no specific cause of action is asserted as to any damages sought by and on behalf of Plaintiff-parent, who is not alleged in the Second Amended Complaint to have suffered any physical injuries as a result of the alleged negligent conduct of Moving Defendants. For this reason, Plaintiff-parent's claim should be dismissed.

Further, even if Plaintiff-parent had properly articulated a cause of action in the Second Amended Complaint to allow her to recover damages in her own right, the Second Amended Complaint should be stricken pursuant to Pa.R.C.P. 1020(b), which provides as follows:

If persons join as plaintiffs under Rules 2228, 2229(a) or (e), the complaint shall state the cause of action, any special damage, and the demand for relief of each plaintiff in a separate count, preceded by a heading naming the parties to the causes of action therein set forth.

Accordingly, it is improper for Plaintiffs to plead in a single count claims on behalf of both the Plaintiff-minor and the Plaintiff-parent, as was done in the Second Amended Complaint filed herein. Claims on behalf of each of the Plaintiffs must be set forth in separate counts of the Second Amended Complaint, specifically identifying the cause of action asserted and relief sought in each count.

ii. **Plaintiff-parent's claims should be dismissed because her claims are time-barred and she has not alleged sufficient facts to demonstrate that the limitations period should be tolled.**

Although the statute of limitations for claims asserted on behalf of minors are tolled until the age of majority, Plaintiff-parent's claims were not similarly tolled and were required to have been brought within two years of the alleged injury. *See Hathi v. Krewstown Park Apts*, 561 A.2d 1261 (Pa. Super. 1989); 42 Pa.C.S. § 5524. Plaintiffs allege that M.E. was born on September 28, 2007, was fed the Defendant Manufacturers' products after her birth, and developed NEC thereafter. *See* Exhibit F, ¶¶ 11-20. Thus, since Plaintiffs' original Complaint was filed on March 24, 2022, Plaintiff-parent's claims herein are clearly time-barred based on the applicable statute of limitations.

In an attempt to circumvent the statute of limitations issues for the Plaintiff-parent, Plaintiffs go to great lengths in their Second Amended Complaint to essentially assert that Plaintiff-parent's claims are somehow preserved by way of the discovery rule. In particular, Plaintiffs allege that Plaintiff-parent did not discover a factual basis for Plaintiffs' negligence claims before the expiration of the limitations period, alleging that Moving Defendants "hid the cause" of M.E.'s NEC diagnosis and thus Plaintiff-parent had "no reason to know or suspect" that the products at issue in this case allegedly caused M.E.'s NEC. *See* Exhibit F, ¶¶ 31-50.

The discovery rule, which is a narrow exception that extends the limitation period in certain limited circumstances, does not apply here. The discovery rule provides that where the existence of the injury is not known to the complaining party and such knowledge cannot reasonably be ascertained within the prescribed period, the period of limitation does not begin to run until discovery of the injury is reasonably possible. *Hayward v. Medical Center of Beaver County*, 608 A.2d 1040, 1043 (Pa. 1992) (abrogated on other grounds).

Under the discovery rule, the statute of limitations is not triggered “until the plaintiff knows or reasonably should know (1) that he or she has been injured, and (2) that this injury has been caused by another party’s conduct.” *See Levenson v. Souser*, 557 A.2d 1081, 1086, 87 (Pa. Super. 1989). The party asserting the discovery rule bears the burden of establishing that he or she falls within it. *See Cochran v. GAF Corp.*, 666 A.2d 245, 249 (Pa. 1995). “[I]t is well-settled that the reasonable diligence standard is objective, as the question is not what the plaintiff actually knew of the injury or its cause, but what he might have known by exercising the diligence required by law.” *Nicolaou v. Martin*, 195 A.3d 880, 893 (Pa. 2018) (citations omitted).

Plaintiffs allege boilerplate accusations that Plaintiff-parent was unable to discover the cause of M.E.’s NEC diagnosis earlier, and therefore, the limitations period is tolled, because “Defendants hid the cause of NEC” from Plaintiff-parent and Defendants “fraudulently concealed” the risks of NEC from Defendant Manufacturer’s products. *See Exhibit F, ¶¶ 31-50*. Plaintiffs do not allege *any* facts to support the claim that Moving Defendants “hid” information from Plaintiff-parent or “fraudulently concealed” any risks from her.

The fatal flaw underlying Plaintiffs’ discovery rule argument is that it presupposes that a risk existed, and Moving Defendants were aware of that risk. However, Plaintiffs have not plead sufficient facts to support this claim, which is also belied by FDA regulations and other statutory

frameworks that exist for the purpose of ensuring the safety of infant formula in the United States. The FDA does not restrict the use of cow's milk-based products for premature or low birth weight infants, and any of Plaintiffs' allegations to the contrary are completely unsupported and baseless.

Based on the foregoing, Plaintiffs have failed to plead sufficient facts to demonstrate that the applicable limitations period should be tolled.

F. MOTION TO STRIKE PLAINTIFFS' COMPLAINT FOR FAILURE TO COMPLY WITH PA.R.C.P. 1024

Pennsylvania Rule of Civil Procedure 1024(a) requires verification of every pleading containing a factual averment based upon the signer's personal knowledge or information and belief. Rule 1024(c) requires that the verification be made by one or more of the parties filing the pleading. In this case, no verification is attached to the Second Amended Complaint in violation of Rule 1024. *See* Exhibit F. Accordingly, the Second Amended Complaint should be stricken for lack of an appropriate verification.

V. REQUESTED RELIEF

For the foregoing reasons, Defendants the Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital and the Trustees of the University of Pennsylvania d/b/a Penn Medicine respectfully request that this Honorable Court sustain their Preliminary Objections and enter the attached Order.

BURNS WHITE LLC

BY: /s/ Meredith A. Lowry

JAMES A. YOUNG, ESQ.

RICHARD S. MARGULIES, ESQ.

MEREDITH A. LOWRY, ESQ.

Attorneys for Defendants,

The Pennsylvania Hospital of the University of

Pennsylvania Health System d/b/a Pennsylvania

Hospital and The Trustees of the University of

Pennsylvania d/b/a Penn Medicine

Dated: August 6, 2024

CERTIFICATE OF SERVICE

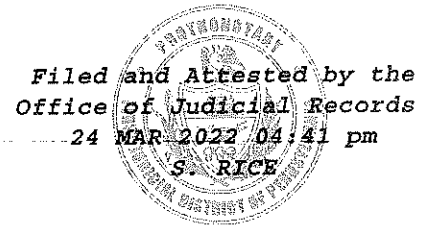
I, Meredith A. Lowry, Esquire, do hereby certify that on this day I caused a true and correct copy of the foregoing Preliminary Objections of Defendants The Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital and The Trustees of the University of Pennsylvania d/b/a Penn Medicine to Plaintiffs' Second Amended Complaint, to be served via the electronic filing system to all counsel of record.

BY: /s/ Meredith A. Lowry
MEREDITH A. LOWRY, ESQ.

Dated: August 6, 2024

EXHIBIT A

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ATTORNEY FOR PLAINTIFFS

ALICE STILLIS, on her own behalf and as
Parent and Natural Guardian of M.E.,
a Minor
656 N. Conestoga Street
Philadelphia, PA 19131
Plaintiffs

v.

MEAD JOHNSON & COMPANY, LLC
Illinois Corporation Service Co.
801 Adlai Stevenson Drive
Springfield, IL 62703

MEAD JOHNSON NUTRITION COMPANY
Illinois Corporation Service Co.
801 Adlai Stevenson Drive
Springfield, IL 62703

ABBOTT LABORATORIES
CT Corporation System
208 So. Lasalle Street, Suite 814
Chicago, IL 60604

COURT OF COMMON PLEAS
PHILADELPHIA COUNTY

CIVIL ACTION

NO.

THE PENNSYLVANIA HOSPITAL OF
THE UNIVERSITY OF PENNSYLVANIA
HEALTH SYSTEM d/b/a PENNSYLVANIA
HOSPITAL
3400 Civic Center Blvd.
Philadelphia, PA 19104

THE TRUSTEES OF THE UNIVERSITY OF
PENNSYLVANIA d/b/a PENN MEDICINE
133 South 36th Street
Philadelphia, PA 19104

Defendants

JURY TRIAL DEMANDED

COMPLAINT IN CIVIL ACTION

NOTICE TO DEFEND

NOTICE

You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you by the court without further notice for any money claimed in the complaint or for any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER OR CANNOT AFFORD ONE, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW TO FIND OUT WHERE YOU CAN GET LEGAL HELP.

PHILADELPHIA BAR ASSOCIATION
LAWYER REFERRAL AND INFORMATION SERVICE
ONE READING CENTER
PHILADELPHIA, PA 19107
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AVISO

Le han demandado a usted en la corte. Si usted quiere defenderse de estas demandas expuestas las páginas siguientes, usted tiene veinte (20) días de plazo al partir de la fecha de la demanda y la notificación. Hace falta asentar una comparencia escrita o en persona o con un abogado y entregar a la corte en forma escrita sus defensas o sus objeciones a las demandas en contra de su persona. Sea avisado que si usted no se defiende, la corte tomará medidas y puede continuar la demanda en contra suya sin previo aviso o notificación. Además, la corte puede decidir a favor del demandante y requiere que usted cumpla con todas las provisiones de esta demanda. Usted puese perder dinero o sus propiedades u otros derechos importantes para usted.

LLEVE ESTA DEMANDA A UN ABOGADO INMEDIATAMENTE. SI NO TIENE ABOGADO O SI NO TIENE EL DINERO SUFICIENTE DE PAGAR TAL SERVICIO, VAYA EN PERSONA O LLAME POR TELEPHONO A LA OFICINA CUYA DIRECCION SE ENCUENTRA ESCRITA ABAJO PARA AVERIGUAR DONDE SE PUEDE CONSEGUIR ASISTENCIA LEGAL.

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ALICE STILLS, ON HER OWN BEHALF
AND AS PARENT AND NATURAL GUARDIAN
OF M.E., A MINOR
656 N. CONESTOGA STREET
PHILADELPHIA, PA 19131

PLAINTIFFS

V.

MEAD JOHNSON & COMPANY, LLC
ILLINOIS CORPORATION SERVICE Co.
801 ADLAI STEVENSON DRIVE
SPRINGFIELD, IL 62703

MEAD JOHNSON NUTRITION COMPANY
ILLINOIS CORPORATION SERVICE Co.
801 ADLAI STEVENSON DRIVE
SPRINGFIELD, IL 62703

ABBOTT LABORATORIES
CT CORPORATION SYSTEM
208 SO. LASALLE STREET, SUITE 814
CHICAGO, IL 60604

THE PENNSYLVANIA HOSPITAL OF
THE UNIVERSITY OF PENNSYLVANIA
HEALTH SYSTEM D/B/A PENNSYLVANIA

COURT OF COMMON PLEAS
PHILADELPHIA COUNTY

CIVIL ACTION

NO.

HOSPITAL
3400 CIVIC CENTER BLVD.
PHILADELPHIA, PA 19104

**THE TRUSTEES OF THE UNIVERSITY OF
PENNSYLVANIA D/B/A PENN MEDICINE
133 SOUTH 36TH STREET
PHILADELPHIA, PA 19104**

DEFENDANTS

JURY TRIAL DEMANDED

COMPLAINT

Plaintiff brings this Complaint and Demand for Jury Trial (the “Complaint”) against Mead Johnson & Company, LLC, Mead Johnson Nutrition Company, and Abbott Laboratories (collectively “the Defendant Manufacturers”), and The Trustees of the University of Pennsylvania d/b/a Penn Medicine and Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital (collectively “Penn Medicine” or “Pennsylvania Hospital”), together “Defendants.” Plaintiff alleges the following upon personal knowledge as to Plaintiff’s own acts and experiences and upon information and belief, including investigation conducted by Plaintiff’s attorneys, as to all other matters.

I. INTRODUCTION

1. This action arises out of the injuries suffered by a premature infant (the “Injured Infant”) who was given the Defendant Manufacturers’ cow’s milk-based infant feeding products at Pennsylvania Hospital. Pennsylvania Hospital, managed by Penn Medicine, acquired and supplied the Defendant Manufacturers’ products to the Injured Infant and negligently failed to warn of their unreasonably dangerous properties in a reasonable manner. This caused the Injured Infant to develop necrotizing enterocolitis (“NEC”), a life-altering and potentially deadly disease that largely affects premature babies who are given cow’s milk-based feeding products. As a result,

the Injured Infant was seriously injured, resulting in long term health effects and accompanying harm to their parent (“the Plaintiff Parent”).

2. Plaintiff brings these causes of action against Defendants to recover for injuries that are the direct and proximate result of the Injured Infant’s consumption of the Defendant Manufacturers’ unreasonably dangerous cow’s milk-based infant feeding products, which were acquired and supplied without adequate warning to the Injured Infant at Pennsylvania Hospital, owned and operated by Penn Medicine.

II. PARTIES

3. Plaintiff Alice Stills is a natural adult person and a resident of Pennsylvania. Ms. Stills is the parent and natural guardian of M.E., a minor. Ms. Stills’ address is 656 N Conestoga Street, Philadelphia, Pennsylvania 19131.

4. Defendant Mead Johnson Nutrition Company is a corporation, incorporated under the laws of the State of Delaware. Its principal place of business is Illinois. Defendant Mead Johnson & Company, LLC, is a limited liability company, organized under the laws of the State of Delaware. Its citizenship is that of its sole member, Mead Johnson Nutrition Company. Defendants Mead Johnson Nutrition Company and Mead Johnson & Company, LLC, (together, “Mead”) are manufacturers of cow’s milk-based infant feeding products and market many of these products under the “Enfamil” brand name.

5. Defendant Abbott Laboratories (“Abbott”) is a corporation, incorporated under the laws of the State of Illinois. Its principal place of business is in Illinois. Abbott is a manufacturer of cow’s milk-based infant feeding products and markets many of its products under the “Similac” brand name.

6. Defendant The Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital is a non-profit corporation incorporated and registered to do business under the laws of the Commonwealth of Pennsylvania. Its principal place of business is Philadelphia, Pennsylvania. Pennsylvania Hospital is a registered name of The Pennsylvania Hospital of the University of Pennsylvania Health System. The sole member of The Pennsylvania Hospital of the University of Pennsylvania Health System is The Trustees of the University of Pennsylvania.

7. Defendant The Trustees of the University of Pennsylvania d/b/a Penn Medicine is a non-profit corporation registered to do business in the Commonwealth of Pennsylvania. Its principal place of business is Philadelphia, Pennsylvania. Penn Medicine is a registered name of The Trustees of the University of Pennsylvania.

III. JURISDICTION AND VENUE

8. This Court has jurisdiction in this matter pursuant to 42 Pa. C.S.A. § 931. Defendants conduct authorized business in the Commonwealth of Pennsylvania. They have sufficient minimum contacts with and purposefully avail themselves of the markets of this Commonwealth. This suit arises out of Defendants' forum-related activities, such that the Court of Common Pleas of Philadelphia County's exercise of jurisdiction would be consistent with traditional notions of fair play and substantial justice.

9. Venue is proper in the Court of Common Pleas of Philadelphia County pursuant to Rules 1006(b), 1006(c)(1), and 2179(a) of the Pennsylvania Rules of Civil Procedure because Defendants are corporations or similar entities that regularly conduct business in Philadelphia County, which is also the county where Plaintiff's causes of action arose, and the county where the occurrences took place out of which Plaintiff's causes of action arose.

10. This action is not subject to the Compulsory Arbitration Program of the Court of Common Pleas of Philadelphia County because the amount in controversy, excluding interest and costs, is in excess of \$50,000.

IV. FACTUAL ALLEGATIONS

M.E.'s NEC Diagnosis

11. M.E. was born prematurely at Pennsylvania Hospital in Philadelphia, Pennsylvania on September 28, 2007.

12. Upon information and belief M.E. was fed Similac and/or Enfamil cow's milk-based products by staff at Pennsylvania Hospital from shortly after his birth.

13. Upon information and belief shortly after M.E. first ingested the Defendant Manufacturers' products, he developed NEC.

Cow's Milk-Based Feeding Products Are Known to Cause NEC

14. NEC is a devastating disease that is the most frequent and lethal gastrointestinal disorder affecting preterm infants. NEC develops when harmful bacteria breach the walls of the intestine, causing portions of the intestine to become inflamed and often to die. Once NEC develops, the condition can progress rapidly from mild feeding intolerance to systemic and fatal sepsis. Up to 30 percent of NEC-diagnosed infants die from the disease.

15. Preterm and low-birth-weight infants are especially susceptible to NEC because of their underdeveloped digestive systems. Extensive scientific research, including numerous randomized controlled trials, has confirmed that cow's milk-based feeding products cause NEC in preterm and low-birth-weight infants, which in turn may lead to other medical complications, surgeries, long-term health problems, and death.

16. For example, in one randomized, multicenter study of 926 preterm infants, NEC was six to ten times more common in exclusively cow's milk formula-fed babies than in exclusively breast milk-fed babies and three times more common in babies who received a combination of formula and breast milk. For babies born at more than 30 weeks gestation, NEC was 20 times more common in those only fed cow's milk formula than in those fed breast milk.

17. Another randomized controlled trial showed that preterm babies fed an exclusive breast milk-based diet were 90% less likely to develop surgical NEC (NEC that requires surgical treatment), compared to preterm babies fed a diet that included some cow's milk-based products.

18. Yet another study that analyzed the data from a 12-center randomized trial concluded that fortification of breast milk with a cow's milk-based fortifier resulted in a 4.2-fold increased risk of NEC and a 5.1-fold increased risk of surgical NEC or death, compared to fortification with a breast milk-based fortifier.

19. A Surgeon General report, The Surgeon General's Call to Action to Support Breastfeeding, warns that, "for vulnerable premature infants, formula feeding is associated with higher rates of necrotizing enterocolitis." The report also states that premature infants who are not breastfed are 138% more likely to develop NEC.

20. The American Academy of Pediatrics, "an organization of 67,000 pediatricians committed to the optimal physical, mental, and social health and well-being for all infants, children, adolescents, and young adults," has advised that all premature infants should be fed either their mother's milk or, if their mother's milk is unavailable, pasteurized human donor milk. This recommendation is based on the "potent benefits of human milk," including "lower rates of . . . NEC."

21. A multicenter, randomized, controlled trial found that premature and low-birth-weight infants fed an exclusive breast milk-based diet suffered NEC only 3% of the time while premature and low-birth-weight infants receiving cow's milk-based formula suffered NEC 21% of the time.

22. Another study conducted a randomized comparison of extremely preterm infants who were given either (a) a diet of breast milk fortified with a breast milk-based fortifier or (b) a diet containing variable amounts of cow's milk-based products. The babies given exclusively breast milk products suffered NEC 5% of the time. The babies given cow's milk products suffered NEC 17% of the time.

Safer, Nutritionally Superior Alternatives To Cow's Milk-Based Products Exist

23. A range of options are available that allow preterm and low-birth-weight infants to be fed exclusively human milk-based nutrition. For example, in addition to the mother's own milk, an established network delivers pasteurized donor breast milk to hospitals nationwide. Moreover, hospitals have access to shelf-stable formula and fortifiers derived from pasteurized breast milk.

24. A diet based exclusively on breast milk and breast milk fortifiers provides all the nutrition necessary to support premature and low-birth-weight infants without the elevated risk of NEC associated with cow's milk-based products. For example, in a study analyzing preterm infants who were fed an exclusive breast milk-based diet until they reached 34 weeks, all 104 infants exceeded standard growth targets and met length and head-circumference growth targets, demonstrating that infants can achieve and mostly exceed targeted growth standards when receiving an exclusive breast milk-based diet. This is particularly true given the ability of breast milk-based fortifiers to provide the additional nutritional supplements necessary for adequate growth while receiving the protective benefits of a breast milk diet.

25. The Defendant Manufacturers' products not only pose a threat to infants' health, but also displace the breast milk they could otherwise receive. This displacement only increases infants' vulnerability to NEC, as studies show that breast milk protects against the disease. For example, a study analyzing 1,587 infants across multiple institutions concluded that an exclusive breast milk-based diet is associated with significant benefits for extremely premature infants and that it produced no feeding-related adverse outcomes.

26. For the above reasons, experts acknowledge that breast milk is the best source of nutrition for preterm infants and those at risk for NEC. Breast milk-based nutrition nourishes infants while creating a significantly lower risk of NEC.

27. At the time the Injured Infant was fed the Defendant Manufacturers' products, the science clearly demonstrated to Defendants that these products cause NEC and greatly increase the likelihood that a baby will develop NEC, leading to severe injury and often death.

28. Despite the scientific consensus that the Defendant Manufacturers' cow's milk-based products present a dire threat to the health and development of preterm infants, the Defendant Manufacturers have made no changes to their products or the products' packaging, guidelines, instructions, or warnings. Instead, they have continued to sell their unreasonably dangerous products. In addition, they incentivize hospitals that know the risks to use their products by providing them to the hospital for free or at a significant discount, in order that vulnerable infants and their families will become accustomed to using their products before discharge.

***The Defendant Manufacturers' False And Misleading Marketing
Regarding Cow's Milk-Based Infant Products***

29. Abbott and Mead have aggressively marketed their cow's milk-based products as medically endorsed and nutritionally equivalent alternatives to breast milk, including prior to the Injured Infant's birth.

30. Abbott's and Mead's marketing approach includes targeting the parents of preterm infants while they are still in the hospital with messages that the Defendant Manufacturers' cow's milk formulas and fortifiers are necessary for the growth and development of their vulnerable children. Often these tactics implicitly discourage mothers from breastfeeding, which reduces the mother's supply of breast milk. None of the Defendant Manufacturers' marketing materials, including their promotional websites, reference the science showing how significantly their products increase the risk of NEC.

31. Numerous studies have shown the detrimental impact of formula advertising on the rates of initiation and continuation of breastfeeding, including studies that show that as "hand feeding" (non-breastfeeding) advertisements increase, reported breastfeeding rates decrease in the following year.

32. Undoubtedly aware of the impact of their advertising, the Defendant Manufacturers, along with other formula manufacturers, are willing to spend massive sums to disseminate their message, with one study estimating that formula manufacturers collectively spent \$4.48 billion on marketing and promotion in 2014 alone.

33. Recognizing the abuse and dangers of infant formula marketing, in 1981, the World Health Assembly—the decision-making body of the World Health Organization—developed the International Code of Marketing of Breast-milk Substitutes ("the Code"), which required companies to acknowledge the superiority of breast milk, the negative effect on breastfeeding of introducing partial bottle-feeding, and the difficulty of reversing the decision not to breastfeed. The Code also forbade advertising or other forms of promotion of formula to the general public, as well as providing sample products to mothers or members of their families.

34. While Abbott and Mead acknowledge the Code on their websites and claim to support the effort to encourage mothers to breastfeed for as long as possible, this is little more than lip service. Instead, the Defendant Manufacturers' aggressive marketing exploits new parents' darkest fears—that the nutrition they are supplying to their child will not provide the best chance of survival—while wholly failing to warn that their products come with a significantly increased risk of NEC.

35. For example, Abbott's website, on a page titled "Infant Formula Marketing," states: "We agree with the World Health Organization that breastfeeding provides the best nutrition for babies, and we support its goal to increase breastfeeding. We also recognize that for infants who aren't breastfed—for medical reasons or otherwise—infant formula is the only appropriate, safe alternative to meet babies' nutritional needs." This statement ignores the existence of donor milk, as well as human milk-based formula.

36. Abbott markets and sells multiple products specifically targeting preterm and low-birth-weight infants, including Liquid Protein Fortifier, Similac NeoSure, Similac Human Milk Fortifiers, Similac Special Care 20, Similac Special Care 24, Similac Special Care 24 High Protein, and Similac Special Care 30. In advertising these products, Abbott emphasizes the products' purported ability to assist underdeveloped babies in reaching their growth targets. For example, on the since-edited webpage regarding Similac NeoSure, Abbott noted: "Your premature baby didn't get her full 9 months in the womb, so her body is working hard to catch up. During her first full year, feed her Similac NeoSure, a nutrient-enriched formula for babies who were born prematurely, and help support her development." Yet, no mention was made of the accompanying significantly increased risk of NEC. At some point, the website was edited to remove this statement. However, upon information and belief, the statement remained on the website until at least December 2020.

37. Mead markets and sells multiple products specifically targeting premature infants, including Enfamil NeuroPro EnfaCare Infant Formula, Enfamil Premature Infant Formula 24 Cal High Protein, Enfamil Premature Infant Formula 30 Cal with Iron, Enfamil Premature Infant Formula 24 Cal with Iron, Enfamil Premature Infant Formula 20 Cal with Iron, Enfamil 24 Cal Infant Formula, and Enfamil Human Milk Fortifier (acidified liquid and powder). In advertising these products, Mead emphasizes the purported similarities between its formula and breast milk, while failing to include any information about the nutritional deficits and dangers that accompany formula use. For example, the since-edited webpage for Enfamil Enfacare stated: “Premature babies fed Enfamil® formulas during the first year have achieved catch-up growth similar to that of full term, breastfed infants” and noted that Enfamil formulas include “expert-recommended levels of DHA and ARA (important fatty acids found naturally in breast milk) to support brain and eye development.”

38. One Enfamil advertisement, introducing a new product line called Enfamil NeuroPro, is entirely focused on favorably comparing Enfamil’s formula to breast milk, without any mention of the product’s extreme risks. Indeed, the terms “human milk” and “breast milk” are used 13 times in the advertisement, including in such statements as “for decades human milk has inspired the advancements in Enfamil formulas and now through extensive global research, we are taking an even closer look at human milk” and “only Enfamil NeuroPro has a fat blend of MFGM and DHA previously found only in breast milk.” The webpage for the product has made similar manipulative claims, stating “Enfamil is backed by decades of breast milk research and multiple clinical studies” and it claims that “to create our best formulas, we collaborated on some of the most extensive breast milk studies to date[.]”

39. Formula manufacturers have long used their relationships with hospitals and the discharge process to encourage parents to substitute formula for breast milk. They offer free or reduced-cost formula to hospitals for use with infants before discharge. And they offer free formula, coupons, and even entire gift baskets to parents before their infants' discharge from the NICU or hospital.

40. Through this early targeting, the Defendant Manufacturers create brand loyalty under the guise of a "medical blessing," in hopes that new parents continue to use formula after they leave the hospital, resulting in increased expense for parents, significantly increased risk for babies, and increased profit for the Defendant Manufacturers. The Defendant Manufacturers' giveaways and gift baskets send confusing signals to mothers who are simultaneously being encouraged to breastfeed by their healthcare professionals, and they have been shown to negatively impact breastfeeding rates.

41. Further, when the Defendant Manufacturers recognized a shift in the medical community towards an exclusive breast milk-based diet for premature infants, Abbott developed a product called "Similac Human Milk Fortifier," and Mead developed "Enfamil Human Milk Fortifier." These names are misleading in that they suggest that the products are derived from breast milk, when, in fact, they are cow's milk-based products. One study, for example, found that only 8.8 percent of parents surveyed in the NICU interpreted "human milk fortifier" as potentially meaning a cow's milk-based product. The packaging appears as:



42. The Defendant Manufacturers have designed powerful misleading marketing campaigns to deceive parents into believing that: (1) cow's milk-based products are safe, including for preterm infants; (2) cow's milk-based products are equal, or even superior, substitutes to breast milk; (3) cow's milk-based products are necessary for proper growth and development of preterm infants; and (4) physicians consider the Defendant Manufacturers' cow's milk-based products to be a first choice. This marketing scheme is employed despite all Defendants knowing of and failing to warn of the extreme risk of NEC and death that cow's milk-based products pose to preterm infants like the Injured Infant.

The Defendant Manufacturers' Inadequate Warnings

43. Although Mead promotes an aggressive marketing campaign designed to convince parents that its cow's milk-based products are safe and necessary for the growth of a premature infant, the product is in fact extremely dangerous for premature infants. Enfamil products significantly increase the chances of a premature infant developing potentially fatal NEC.

44. The Enfamil products Mead markets specifically for premature infants are commercially available at retail locations and online. No prescription is necessary.

45. Despite knowing of the risk of NEC, the packaging of Mead's products does not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with Mead's products, or of the magnitude of this increased risk. Mead likewise did not provide instructions or guidance for how to avoid NEC.

46. Mead cites no medical literature or research to guide the use of its products.

47. Despite knowing of the risk of NEC, Mead did not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with its products, or of the magnitude of this increased risk. Mead likewise did not provide instructions or guidance for how to avoid NEC.

48. Mead deceived the public, parents, physicians, other medical professionals, and medical staff into believing that Enfamil products were a safe and necessary alternative, supplement and/or substitute to breast milk.

49. Despite knowing that its products were being fed to premature infants, often without the parents' informed consent, Mead failed to require or recommend that medical professionals inform parents of the significant risk of NEC or to require that parental consent be obtained prior to the products being fed to their babies.

50. Like Mead, Abbott promotes an aggressive marketing campaign designed to make parents believe that its products are safe and necessary for the growth of premature infants, despite the products in fact being extremely dangerous for premature infants. Abbott's products significantly increase the chances of a premature infant getting potentially fatal NEC.

51. The products Abbott markets specifically for premature infants are available at retail locations and online. No prescription is necessary.

52. Despite knowing of the risk of NEC, Abbott did not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with its products, or of the magnitude of this increased risk. Abbott likewise did not provide instructions or guidance for how to avoid NEC.

53. Abbott deceived the public, parents, physicians, other medical professionals, and medical staff into believing that its products were a safe and necessary alternative, supplement and/or substitute to breast milk.

54. Despite knowing that its products were being fed to premature infants, often without the parents' informed consent, Abbott failed to require or recommend that medical professionals inform parents of the significant risk of NEC or to require that parental consent be obtained prior to the products being fed to their babies.

Penn Medicine's Failure to Warn

55. On information and belief, Penn Medicine, which operates Pennsylvania Hospital, was aware of the significantly increased risk of NEC and death associated with providing Abbott's and Mead's cow's milk-based products to its premature infant patients. It knew or should have known that feeding these cow's milk-based products can cause NEC in premature infants who otherwise would not have developed this devastating condition. However, instead of warning of those

dangers, or supplying breast milk-based feeding products to preterm infants like the Injured Infant, Penn Medicine has continued to source, distribute, and supply the Defendant Manufacturers' products in its hospitals without any adequate warning.

56. To that end, Penn Medicine has participated in studies designed to increase the use of donor milk while, at the same time, reducing formula feeding in neonates. The University of Pennsylvania School of Nursing, an affiliate of Penn Medicine, has conducted extensive research into the risks associated with feeding formula to premature infants. It recently partnered with the National Institute of Nursing Research to publish clinical determinations based on its experience "changing hospital systems and influencing policy," and its findings were unequivocal:

This is what we know about the science of human milk: it reduces the risk of necrotizing enterocolitis, reduces the risk of infection, [and] creates greater enteral feed tolerance and more rapid weaning from intravenous nutrition. . . .

Other Penn Medicine research has similarly concluded that "[h]uman milk decreases the incidence and severity of . . . necrotizing enterocolitis (NEC)."

57. Penn Medicine also purports to adhere to the tenets of the "Baby Friendly Hospital Initiative," which seeks to increase rates of breastfeeding initiation, exclusivity, and diet duration. The "Baby Friendly Hospital Initiative" specifically targets a reduction in the rates of NEC in preterm infants by encouraging implementation of exclusive breast milk diets among new mothers. Although Pennsylvania Hospital has maintained its "Baby Friendly" designation for years, it has not eliminated or restricted the use of formula or fortifier for preterm infants in its hospitals.

58. Finally, medical providers and staff at Penn Medicine have acknowledged the risks associated with providing the Defendant Manufacturers' cow's milk-based products to premature infant patients instead of breast milk-based nutrition. In an internal newsletter from 2012 touting donor milk programs, Penn Medicine acknowledged the benefits of a human milk-based diet, quoting a staff lactation consultant:

Donor milk is not inexpensive. It costs about \$4.25 per ounce, but the return on investment is huge. “Preemies given mother’s milk get discharged three to four days sooner and also have a six to 10 times lower risk of getting a gastrointestinal complication called necrotizing enterocolitis,” Carpenter said, adding that the infection can cost up to \$250,000 to treat. The average cost to provide a preemie with donor milk: \$125.

59. These statements demonstrate that Penn Medicine knew or should have known of the high increased risk of NEC for premature infants posed by the Defendant Manufacturers’ products.

60. Although Penn Medicine knew or should have known of the serious danger of the Defendant Manufacturers’ products, it has continued to purchase, supply, and distribute these products to preterm infants without providing full and adequate warnings of the attendant risks to parents, healthcare professionals, and other medical staff at its relevant facilities. As a result, the Injured Infant was fed the Defendant Manufacturers’ cow’s milk-based products at Pennsylvania Hospital, causing their injuries. This occurred even though hospitals across the country, including Pennsylvania Hospital, warn and obtain consent from parents before providing other safer forms of nutrition, such as donor breast milk.

61. Penn Medicine’s failure to warn of the risks posed by the Defendant Manufacturers’ products is entrenched (and compounded) by the financial benefits it accrues from its relationships with the Defendant Manufacturers. On information and belief, it has received the Defendant Manufacturers’ cow’s milk-based products for free or at a significant discount, and has granted their sales representatives access to its healthcare professionals and medical staff. These sales representatives have provided deceptive information that Penn Medicine reasonably knew or should have known would ultimately reach parents through those staff. This arrangement dovetails with the Defendant Manufacturers’ own marketing strategy, which aims to “sell and service” healthcare professionals and medical staff as a means of converting them into “extra salespersons.”

Safer Alternative Designs

62. The Defendant Manufacturers' cow's milk-based products made specifically for premature infants are unreasonably unsafe for those infants. The Defendant Manufacturers could have used pasteurized breast milk instead of cow's milk in their products, which would have produced a safer product.

63. Prolacta Bioscience manufactures and sells breast milk-based feeding products, specifically designed for preterm infants, which contain no cow's milk. This alternative design provides all the necessary nutrition for growth and development that cow's milk-based products provide, without the same unreasonably dangerous and deadly effects.

64. On information and belief, Abbott and Mead were aware of the significantly increased risk of NEC and death associated with their cow's milk-based products, and instead of warning of the dangers, or removing them altogether, Abbott and Mead have continued to use cow's milk as the foundation of their products.

CAUSES OF ACTION
COUNT I: STRICT LIABILITY FOR DESIGN DEFECT
(Against Abbott and Mead)

65. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

66. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to manufacture, sell, and distribute their products in a manner that was not unreasonably dangerous.

67. Abbott and Mead also owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to manufacture, sell, and distribute their products in a manner that was merchantable and reasonably suited for their intended use.

68. Abbott and Mead knew that their products would be used to feed premature infants like the Injured Infant and knew (or reasonably should have known) that use of their cow's milk-based products significantly increased the risk of NEC, serious injury, and death, and that such use was therefore unreasonably dangerous to premature infants, not reasonably suited for the use intended, not merchantable, and had risks that exceeded a reasonable buyer's expectations. Nonetheless, they continued to sell and market their defective products as appropriate for premature infants.

69. The Injured Infant ingested Abbott and/or Mead's unreasonably dangerous cow's milk-based products. The risks of feeding those products to the Injured Infant outweighed the benefits. An ordinary consumer would not expect those products to carry a significant risk of serious injury and death from NEC.

70. Abbott and Mead knew (or reasonably should have known) that breast milk-based nutrition did not carry the same risks of NEC, serious injury, and death that their products do.

71. Abbott's and Mead's products contained cow's milk at the time they left the manufacturing facility.

72. Abbott and Mead did not develop a human-milk based product that was safer for premature infants and did not reformulate their products to reduce the risk of NEC, serious injury, and death, even though doing so was economically and technologically feasible and even though pasteurized breast milk was an available alternative.

73. Abbott's and/or Mead's products were fed to the Injured Infant, which caused and/or increased the risk of their NEC and injuries.

74. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT II: STRICT LIABILITY FOR FAILURE TO WARN
(Against Abbott and Mead)**

75. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

76. Abbott and Mead, as the manufacturers and/or sellers of the infant products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide adequate warnings or instructions about the dangers and risks associated with the use of

their products with preterm infants, specifically including but not limited to the risk of NEC, serious injury, and death.

77. Abbott's and Mead's duty to warn is part of their general duty to design, manufacture, and sell their infant products in a manner that is reasonably safe for their foreseeable uses. By designing their products with cow's milk-based ingredients, Abbott and Mead undertook a duty to warn of the unreasonable risk of harm posed by those ingredients, specifically including the significantly increased risk of NEC, severe injury, and death. The failure to warn makes the products at issue in this litigation unreasonably dangerous.

78. Specifically, Abbott and Mead breached their duty to warn of the foreseeable risks of the infant products at issue in this litigation because they knew or should have known that their cow's milk-based premature infant products would be fed to premature infants like the Injured Infant, and that their products might cause the Injured Infant to develop NEC, severe injury, or death, yet they failed to provide adequate warnings of those risks. Among other risks, the Defendant Manufacturers:

- a. Failed to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death for the Injured Infant; and/or
- b. Failed to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or
- c. Inserted warnings and instructions on their products that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC and death; and/or

- d. Failed to insert a large and prominent “black box”-type warning that their cow’s milk-based products are known to significantly increase the risk of NEC and death when compared to breast milk in premature infant; and/or
- e. Failed to disclose well-researched and well-established studies that linked cow’s milk-based products to NEC and death in premature infants; and/or
- f. Failed to insert a warning or instruction to healthcare professionals and other medical staff in the hospital that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers’ products, notwithstanding their substantial risks; and/or
- g. Failed to provide a warning in a method reasonably calculated or expected to reach the parents of newborns, like the Plaintiff Parent; and/or
- h. Failed to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow’s milk-based products.

79. Abbott’s and Mead’s products contained cow’s milk at the time they left the manufacturing facility.

80. As a direct and proximate result of the inadequacy of the warnings and the pervasive marketing campaigns suggesting the safety and necessity of the Defendant Manufacturers’ products, the Injured Infant were fed cow’s milk-based products, which caused them to develop NEC.

81. The unwarned-of risks are not of a kind that an ordinary consumer would expect. Had physicians and medical staff known of the extreme risk associated with feeding premature infants cow’s milk-based formula, they would not have fed the Injured Infant those products. Had the

Plaintiff Parent known of the significant risks of feeding the Injured Infant cow's milk-based formula, they would not have allowed such products to be fed to the Injured Infant.

82. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendants Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT III: NEGLIGENCE
(Against Abbott and Mead)**

83. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

84. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to exercise reasonable care to design, test, manufacture, inspect, and distribute a product free of unreasonable risk of harm to users, when such products are used in their intended manner and for their intended purpose.

85. At all times relevant to this action, the Injured Infant's healthcare professionals and medical staff used the products at issue in their intended manner and for their intended purpose.

86. Abbott and Mead, directly or indirectly, negligently, and/or defectively made, created, manufactured, designed, assembled, tested, marketed, sold, and/or distributed the cow's milk-based infant products at issue in this litigation and thereby breached their duty to the general public and the Plaintiff Parent.

87. Specifically, although Abbott and Mead knew or reasonably should have known at the time of production that their cow's milk-based infant products significantly increased the risk of NEC, serious injury, and death, they failed to act in a reasonably prudent manner and breached their duty by:

- a. Failing to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death for the Injured Infant; and/or
- b. Failing to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or

- c. Inserting warnings and instructions that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC and death; and/or
- d. Failing to insert a large and prominent “black box”-type warning that their cow’s milk-based products are known to significantly increase the risk of NEC and death when compared to breast milk in premature infants; and/or
- e. Failing to provide well-researched and well-established studies that linked cow’s milk-based products to NEC and death in premature infants; and/or
- f. Failing to insert a warning or instruction to healthcare professionals and other medical staff in the hospital that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers’ products, notwithstanding their substantial risks; and/or
- g. Failing to provide a warning in a method reasonably calculated/expected to reach the parents of newborns, like the Plaintiff Parent; and/or
- h. Failing to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow’s milk-based products.

88. In addition, although Abbott and Mead knew or reasonably should have known at the time of production that their cow’s milk-based products significantly increased the risk of NEC, serious injury, and death, they failed to act in a reasonably prudent manner and breached their duty by failing to perform the necessary process of data collection, detection, assessment, monitoring, prevention, and reporting or disclosure of adverse outcomes in infants who ingest their products.

89. As a direct and proximate result of the Defendant Manufacturers' failure to act in a reasonably prudent manner and their breach of duty, the Injured Infant was fed cow's milk-based products, which caused and/or increased the risk of their developing NEC.

90. Had Abbott and Mead satisfied their duties to the consuming public in general, the Injured Infant would not have been exposed to their unreasonably dangerous cow's milk-based products.

91. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendants Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and

g. For such other and further relief as the Court deems proper.

**COUNT IV: INTENTIONAL MISREPRESENTATION
(Against Abbott and Mead)**

92. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

93. At all times relevant to this action, the Injured Infant consumed the Defendant Manufacturers' products in their intended manner and for their intended purpose.

94. Abbott and Mead, as the manufacturers and/or sellers of the infant products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide truthful, accurate, fulsome information about the risks and benefits of using their products when used in the intended manner and for the intended purpose.

95. Abbott and Mead breached their duty through misrepresentations made to consumers, physicians, and medical staff in their advertising and promotional materials, as described in previous paragraphs and incorporated herein, each of whom were foreseeable and intended recipients of this information.

96. Specifically, upon information and belief, Abbott and Mead made the following false statements of material fact on an ongoing and repeated basis and prior to the time the Injured Infant was fed their products:

- a. That their cow's milk-based products were safe and beneficial for premature infants when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or
- b. That their cow's milk-based products were necessary to the growth and nutrition of premature infants, when they knew or should have known that their products were not necessary to achieve adequate growth; and/or

- c. That their products have no serious side effects, when they knew or should have known the contrary to be true; and/or
- d. That cow's milk-based products were safe for premature infants; and/or
- e. That cow's milk-based products were necessary for optimum growth; and/or
- f. That cow's milk-based products were similar or equivalent to breast milk; and/or
- g. That their products were safe and more like breast milk than other infant products and that they had removed the harmful ingredients of cow's milk when, in fact, the cow's milk in their products was still capable of causing NEC, serious injury, and death; and/or
- h. That their products were based on up-to-date science, which made them safe for premature infants; and/or
- i. Omitting the material fact that their products significantly increased the risk of NEC in premature infants.

97. Abbott and Mead knew or reasonably should have known those misrepresentations to be false.

98. The Defendant Manufacturers' misrepresentations were intended to, and in fact did, induce physicians and medical staff, including the Injured Infant's physicians and medical staff, to provide their infant products to babies, including the Injured Infant.

99. The Plaintiff Parent was not aware that these misrepresentations were false and justifiably relied on them. The Defendant Manufacturers' misrepresentations induced the Plaintiff Parent to allow their children to be fed Abbott's and Mead's infant products, in reliance on all the messaging they received about formula feeding, including, directly or indirectly, the Defendant Manufacturers' messaging. Had Abbott and Mead not committed these intentional

misrepresentations, the Injured Infant would not have been exposed to the Defendant Manufacturers' unreasonably dangerous cow's milk-based products.

100. As a direct and proximate result, Abbott's and Mead's products were fed to the Injured Infant, which caused and/or increased risk of their developing NEC and subsequent injuries.

101. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT V: NEGLIGENT MISREPRESENTATIONS
(Against Abbott and Mead)**

102. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

103. At all times relevant to this action, the Injured Infant consumed the products at issue in their intended manner and for their intended purpose.

104. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide truthful, accurate, and complete information about the risks and benefits of using their products when used in the intended manner and for the intended purpose.

105. In the course of their business, Abbott and Mead breached their duty through misrepresentations made to consumers, physicians, and medical staff in their advertising and promotional materials, as described in previous paragraphs and incorporated herein, each of whom were foreseeable recipients of this information.

106. Specifically, upon information and belief, Abbott and Mead made the following false statements of material fact on an ongoing and repeated basis and prior to the time the Injured Infant was fed their products:

- a. That their cow's milk-based products were safe and beneficial for premature infants when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or
- b. That their cow's milk-based products were necessary to the growth and nutrition of premature infants, when they knew or should have known that their products were not necessary to achieve adequate growth; and/or

- c. That their products have no serious side effects, when they knew or should have known the contrary to be true; and/or
- d. That cow's milk-based products were safe for premature infants; and/or
- e. That cow's milk-based products were necessary for optimum growth; and/or
- f. That cow's milk-based products were similar or equivalent to breast milk; and/or
- g. That their products were safe and more like breast milk than other infant products and that they had removed the harmful ingredients of cow's milk when, in fact, the cow's milk in their products was still capable of causing NEC, serious injury, and death; and/or
- h. That their products were based on up-to-date science, which made them safe for premature infants; and/or
- i. Omitting the material fact that their products significantly increased the risk of NEC in premature infants.

107. Abbott and Mead were negligent or careless in not determining those representations to be false.

108. The Defendant Manufacturers' misrepresentations were intended to and did in fact induce physicians and medical staff, including the Injured Infant's physicians and medical staff, to provide their products to babies, including the Injured Infant.

109. The Defendant Manufacturers' misrepresentations induced, and were intended to induce, the Plaintiff Parent to allow their child to be fed Abbott's and Mead's infant products, in justifiable reliance on all the messaging they received about formula feeding, including, directly or indirectly, the Defendant Manufacturers' messaging. Had Abbott and Mead not committed these negligent

misrepresentations, the Injured Infant would not have been exposed to their unreasonably dangerous cow's milk-based products.

110. As a direct and proximate result, Abbott's and Mead's products were fed to the Injured Infant, which caused and/or increased of their developing NEC and subsequent injuries.

111. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT VI: FAILURE TO WARN
(Against Penn Medicine and Pennsylvania Hospital)**

112. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

113. Penn Medicine and Pennsylvania Hospital as purchaser, supplier, and/or distributor of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to purchase, supply, and distribute products that were free of unreasonable risk of harm when used in their intended manner and for their intended purpose, and/or to formulate, adopt, and enforce adequate rules and policies for the same.

114. At all times relevant to this action, the Injured Infant used the cow's milk-based products purchased, supplied, and/or distributed by Penn Medicine and Pennsylvania Hospital in their intended manner and for their intended purpose.

115. Penn Medicine and Pennsylvania Hospital employed or contracted with the healthcare professionals and medical staff at Pennsylvania Hospital, managing these individuals during their treatment of the Injured Infant.

116. Penn Medicine and Pennsylvania Hospital negligently and recklessly supplied and distributed the Defendant Manufacturers' milk-based infant feeding products to these healthcare professionals and medical staff for use on premature infants, including the Injured Infant.

117. Moreover, at all relevant times, Penn Medicine and Pennsylvania Hospital knowingly authorized the Defendant Manufacturers' sales representatives to market, advertise, distribute, and/or sell their products at Pennsylvania Hospital. The Defendant Manufacturers' sales representatives were encouraged to interact with Pennsylvania Hospital's healthcare professionals and medical staff. These interactions provided the Defendant Manufacturers' sales representatives an opportunity to co-opt Pennsylvania Hospital's healthcare professionals and medical staff into

assisting with the marketing, distribution, and/or sale of the Defendant Manufacturers' unreasonably dangerous products to consumers, such as the Plaintiff Parent.

118. Penn Medicine and Pennsylvania also knowingly allowed the Defendant Manufacturers' sales representatives to routinely misrepresent the risks and benefits of Defendants' products to Pennsylvania Hospital's healthcare professionals and medical staff, including the misrepresentation that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

119. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known at the time that they acquired, distributed, and supplied the Defendant Manufacturers' cow's milk-based infant products that these products significantly increased the risk of NEC, serious injury, and death.

120. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, recklessly and breached its duty by:

- a. Failing to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in those babies; and/or
- b. Failing to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or
- c. Failing to warn or instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risk; and/or

- d. Failing to provide its healthcare professionals and medical staff with the well-researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or
- e. Failing to provide a warning in a method reasonably calculated/expected to reach the parents of newborns; and/or
- f. Failing to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products; and/or
- g. Failing to prevent the Defendant Manufacturers' sales representatives from misrepresenting to Pennsylvania Hospital's healthcare professionals and medical staff that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

121. Reasonable hospitals under the same or similar circumstances would have warned of the above risks, would have instructed their healthcare professionals and medical staff—as well as patients—on the safe use of the Defendant Manufacturers' products, and would have restricted the ability of the Defendant Manufacturers' sales representatives to market the Defendant Manufacturers' unreasonably dangerous products without adequate warning.

122. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that its medical professionals and the parents of premature infants, including the Plaintiff Parent, would not have realized the risks associated with feeding cow's milk-based formula to premature infants.

123. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its duty to warn its medical providers and patients about the Defendant Manufacturers' unreasonably dangerous products, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

124. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital's failure to warn of the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

125. As a further direct and proximate result of Penn Medicine and Pennsylvania failure to warn of the Defendant Manufacturers' unreasonably dangerous products, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against Penn Medicine and Pennsylvania Hospital as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of Penn Medicine's conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from Penn Medicine and Pennsylvania Hospital's oppressive, reckless, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;

- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT VII: CORPORATE LIABILITY OF HEALTH-CARE PROVIDER
(Against Penn Medicine and Pennsylvania Hospital)**

126. Plaintiff incorporates by references each of the preceding paragraphs as if fully set forth herein.

127. At all relevant times, Penn Medicine and Pennsylvania Hospital owed a duty of care to the Injured Infant to ensure their safety and well-being while the Injured Infant was under the care of Pennsylvania Hospital staff. Specifically, Penn Medicine and Pennsylvania Hospital had a duty to the Injured Infant to formulate, adopt, and enforce adequate rules and policies to ensure quality care for the Injured Infant. Further, Penn Medicine and Pennsylvania Hospital owed a duty to the Injured Infant to oversee its healthcare professionals and medical staff that provided patient care to the Injured Infant.

128. Penn Medicine and Pennsylvania Hospital owed a duty to its patients, and the Injured Infant in particular, to formulate, adopt, and enforce adequate rules and policies for the purchase, supply, distribution, and use of products that were free of unreasonable risk of harm when used in their intended manner and for their intended purpose and ensured quality care for the Injured Infant.

129. At all times relevant to this action, the Injured Infant used the cow's milk-based products purchased, supplied, and/or distributed by Penn Medicine and Pennsylvania Hospital in their intended manner and for their intended purpose.

130. Moreover, at all relevant times, Penn Medicine and Pennsylvania Hospital knowingly authorized the Defendant Manufacturers' sales representatives to market, advertise, distribute,

and/or sell their products at Pennsylvania Hospital. The Defendant Manufacturers' sales representatives were encouraged to interact with Pennsylvania Hospital's healthcare professionals and medical staff. These interactions provided the Defendant Manufacturers' sales representatives an opportunity to co-opt Pennsylvania Hospital's healthcare professionals and medical staff into assisting with the marketing, distribution, and/or sale of the Defendant Manufacturers' unreasonably dangerous products.

131. Penn Medicine and Pennsylvania Hospital also knowingly allowed the Defendant Manufacturers' sales representatives to routinely misrepresent the risks and benefits of Defendants' products to Pennsylvania Hospital's healthcare professionals and medical staff, including the misrepresentation that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

132. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known at the time that it formulated, adopted, and enforced its rules for the acquisition, distribution, and supply of the Defendant Manufacturers' cow's milk-based infant products, including the access afforded the Defendant Manufacturer's sales representatives, that these products significantly increased the risk of NEC, serious injury, and death for premature infants.

133. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that its medical professionals and the parents of premature infants, including the Plaintiff Parent, would not have realized the risks associated with feeding cow's milk-based formula to premature infants.

134. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, recklessly and breached its duty by:

- a. Failing to formulate, adopt, and enforce adequate rules and policies that would have restricted the use of cow's milk-based products for feeding premature babies; and/or
- b. Failing to formulate, adopt, and enforce adequate rules and policies that warned the Plaintiff Parent that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in premature babies, like the Injured Infant; and/or
- c. Failing to formulate, adopt, and enforce adequate rules and policies that warned its healthcare professionals and medical staff that cow's milk-based products are unsafe and/or contraindicated for premature babies like the Injured Infant; and/or
- d. Failing to formulate, adopt, and enforce adequate rules and policies to instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risk; and/or
- e. Failing to formulate, adopt, and enforce adequate rules and policies to provide its healthcare professionals and medical staff with the well-researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or
- f. Failing to formulate, adopt, and enforce adequate rules and policies to ensure a warning in a method reasonably calculated/expected to reach the parents of newborns, like the Plaintiff Parent; and/or
- g. Failing to formulate, adopt, and enforce adequate rules and policies to prevent the Defendant Manufacturers' sales representative from misrepresenting to

Pennsylvania Hospital's healthcare professionals and medical staff that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants; and/or

- h. Failing to establish a donor milk program that was sufficient to meet the needs of the premature babies, like the Injured Infant.

135. A reasonable hospital under the same or similar circumstances would have formulated, adopted, and enforced adequate policies, and rules to restrict the feeding of cow's milk-based products to premature babies, including developing an adequate donor milk program, instructing its healthcare professionals and medical staff on the safe use of Defendants Manufacturers' cow's milk-based products, and restricting the marketing of the Defendant Manufacturers' unreasonably dangerous products to its healthcare professionals, medical staff, and parents of premature infants under its care.

136. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its duty to formulate, adopt, and enforce adequate rules and policies to ensure the quality care of its patients, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

137. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital failure to formulate and enforce adequate policies and rules related to the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

138. As a further direct and proximate result of Penn Medicine and Pennsylvania Hospital negligent and reckless conduct the Plaintiff Parent suffered significant emotional distress, loss of

income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

139. In the alternative, Penn Medicine and Pennsylvania Hospital owed a duty to its patients, and the Injured Infant in particular, to oversee the practicing healthcare professionals and medical staff that provided the products at issue to infants under Pennsylvania Hospital's care, including the Injured Infant.

140. Penn Medicine and Pennsylvania Hospital employed or contracted with the healthcare professionals and medical staff at Pennsylvania Hospital and was responsible for overseeing those individuals during their treatment of the Injured Infant.

141. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, recklessly and breached its duty by:

- a. Failing to oversee its healthcare professionals and medical staff on their use of cow's milk-based products for feeding premature babies; and/or
- b. Failing to warn or instruct its healthcare professionals and medical staff that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in those babies; and/or
- c. Failing to warn or instruct its healthcare professionals and medical staff that cow's milk-based products are unsafe and/or contraindicated for premature babies like the Injured Infant; and/or
- d. Failing to oversee its healthcare professionals and medical staff to restrict their feeding of cow's milk-based products to premature babies; and/or
- e. Failing to warn or instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice

about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risk; and/or

- f. Failing to provide its healthcare professionals and medical staff with the well-researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or
- g. Failing to provide its healthcare professionals and medical staff with warnings about the dangers of the Defendants' Manufacturers products in a method reasonably calculated/expected to reach the parents of newborns; and/or
- h. Failing to provide statistical evidence to its healthcare professionals and medical staff showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products; and/or
- i. Failing to oversee its healthcare professionals and medical staff to ensure that the Defendant Manufacturers' sales representatives' misrepresentations that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants had not influenced the use and/or misuse of the Defendant Manufacturers' products.

142. A reasonable hospital under the same or similar circumstances would have warned of the above risks, would have instructed its healthcare professionals and medical staff on the safe use of the Defendant Manufacturers' products, and would have restricted the ability of the Defendant Manufacturers' sales representatives to market the Defendant Manufacturers' unreasonably dangerous products without adequate warning.

143. A reasonable hospital under the same or similar circumstances would have overseen and managed its healthcare professionals and medical staff to ensure that they received proper training and updating on the risks associated with feeding cow's milk-based formula to premature infants.

144. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its duty to oversee its healthcare professionals and medical staff who provide patient care, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

145. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital's failure to oversee its healthcare professionals and medical staff on the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

146. As a further direct and proximate result of Penn Medicine and Pennsylvania Hospital's negligent and reckless conduct, , the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against Penn Medicine and Pennsylvania Hospital as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of Penn Medicine and Pennsylvania Hospital's conduct;

- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from Penn Medicine's oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

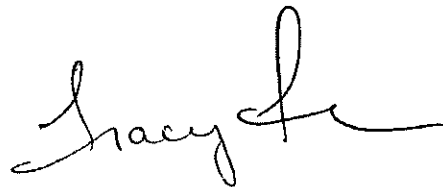
DEMAND FOR JURY TRIAL

147. Plaintiff hereby demands a jury trial for all claims triable.

Dated: March 24, 2022

Respectfully submitted,

ANAPOL WEISS



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Attorneys for Plaintiff

CERTIFICATE OF SERVICE

I hereby certify that on March 24, 2022, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF and that the foregoing document is being served on all counsel of record or parties registered to receive CM/ECF Electronic Filings.

A handwritten signature in black ink, appearing to read "Tracy Finken", written over a horizontal line.

Tracy Finken

VERIFICATION

I, the undersigned, Tracy Finken, verify that the statements made in this document are true and correct to the best of my knowledge, information, and belief. I understand that false statements herein are made subject to the penalties of 18 Pa. C.S. §4904, relating to unsworn falsification to authorities.

A handwritten signature in black ink, appearing to read "Tracy Finken", written over a horizontal line.

Tracy Finken

Date: March 24, 2022

EXHIBIT B

Alice Stills, on her own behalf and as Parent
and Natural Guardian of M.E., a minor

Plaintiffs

v.

MEAD JOHNSON & COMPANY, LLC, et
al.

Defendants.

COURT OF COMMON PLEAS
PHILADELPHIA COUNTY

CIVIL DIVISION

MARCH TERM, 2022
NO. 2617



ORDER

AND NOW, this day of 2023, upon consideration of the Preliminary Objections of Defendants The Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital and The Trustees of the University of Pennsylvania d/b/a Penn Medicine to Plaintiffs' Complaint, and any Response thereto, it is hereby **ORDERED** that the Preliminary Objections are **SUSTAINED**. It is further **ORDERED** that all claims against Defendants the Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital and The Trustees of the University of Pennsylvania d/b/a Penn Medicine are hereby **DISMISSED** with prejudice.

BY THE COURT:

J.

Alice Stills, on her own behalf and as Parent
and Natural Guardian of M.E., a minor

Plaintiffs

v.

MEAD JOHNSON & COMPANY, LLC, et
al.

Defendants.

COURT OF COMMON PLEAS
PHILADELPHIA COUNTY

CIVIL DIVISION

MARCH TERM, 2022
NO. 2617

ALTERNATIVE ORDER

AND NOW, this day of 2023, upon consideration of the Preliminary Objections of Defendants The Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital and The Trustees of the University of Pennsylvania d/b/a Penn Medicine to Plaintiffs' Complaint, and any Response thereto, it is hereby **ORDERED** that the Preliminary Objections are **SUSTAINED**. It is further **ORDERED** that:

1. Count VI of Plaintiffs' Complaint is **DISMISSED** with prejudice;
2. Count VII of Plaintiffs' Complaint is **DISMISSED** with prejudice;
3. Plaintiffs' claims for punitive damages as to Defendants The Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital and The Trustees of the University of Pennsylvania d/b/a Penn Medicine are **DISMISSED** with prejudice, along with all allegations of oppressive, reckless, malicious and/or fraudulent conduct;
4. Plaintiff Alice Stills' claims in her own right are **DISMISSED** with prejudice; and
5. Plaintiffs' Complaint is **STRICKEN** for lack of an appropriate verification.

BY THE COURT:

J.

BURNS WHITE LLC
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Pennsylvania Health System d/b/a Pennsylvania
Hospital and The Trustees of the University of
Pennsylvania d/b/a Penn Medicine

Alice Stills, on her own behalf and as Parent
and Natural Guardian of M.E., a minor

Plaintiffs

v.

MEAD JOHNSON & COMPANY, LLC, et
al.

Defendants.

COURT OF COMMON PLEAS
PHILADELPHIA COUNTY

CIVIL DIVISION

MARCH TERM, 2022
NO. 2617

**PRELIMINARY OBJECTIONS OF DEFENDANTS THE PENNSYLVANIA HOSPITAL
OF THE UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM AND THE
TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA
TO PLAINTIFFS' COMPLAINT**

Defendants The Pennsylvania Hospital of the University of Pennsylvania Health System
("Pennsylvania Hospital") and the Trustees of the University of Pennsylvania (hereinafter
"Moving Defendants") hereby preliminarily object to Plaintiffs' Complaint, and, in support
thereof, aver as follows:

I. INTRODUCTION

1. Plaintiffs instituted this action via the filing of a Complaint on March 24, 2022
against Moving Defendants as well as Co-Defendants Mead Johnson & Company, LLC, Mead

Johnson Nutritional Company (collectively referred to as “Mead Johnson”) and Abbott Laboratories (“Abbott”). See Plaintiff’s Complaint, attached as Exhibit “A.”¹

2. Plaintiffs have filed a slew of essentially identical lawsuits against Pennsylvania Hospital and other hospitals in Philadelphia based on claims relating to alleged ingestion of cow’s milk-based infant formula by premature infants following their birth.²

3. Plaintiffs allege that “upon information and belief” the Plaintiff-minors, including M.E., were diagnosed with necrotizing enterocolitis (NEC), a gastrointestinal disorder that premature infants are at increased risk to develop. *See* Plaintiffs’ Complaint, attached as Exhibit “A,” ¶ 13. Plaintiffs allege that premature infants fed with their mother’s breast milk or donor breast milk are at decreased risk of developing NEC as compared with infants given cow’s milk-based infant formula.³

4. In addition to asserting product liability claims against the infant formula manufacturers Mead Johnson and Abbott, Plaintiffs have alleged that Moving Defendants are liable based on theories of failure to warn and corporate liability.⁴

¹ Shortly after the filing of the Complaint, this case was removed to federal court. Following briefing and a hearing, the case was remanded to this Honorable Court. There was then an effort by all Defendants to transfer these cases to this Court’s Mass Tort Program. Plaintiffs opposed this request, and same was denied by this Honorable Court.

These preliminary objections were timely filed after the initial filing of the Complaint, but never ruled upon.

² Lawsuits involving identical claims have been filed against the Hospital of the University of Pennsylvania, Temple University Hospital, Albert Einstein Medical Center and Thomas Jefferson University Hospital.

³ Although Plaintiffs aver in the Complaint that NEC is caused by cow’s milk-based infant formula, as discussed *infra* and in the accompanying Memorandum of Law, the allegations in the Complaint refer to research and studies that indicate only that NEC is *more common* in premature and low birth weight infants fed with cow’s milk-based products as compared with similar infants fed with breast milk. *See* Exhibit “A,” ¶¶ 17-23. Plaintiffs do not cite any study or statement in the Complaint that indicates NEC is caused by cow’s milk-based infant formula.

⁴ As is discussed in detail in the accompanying Memorandum of Law, infant formulas are regulated by the United States Food and Drug Administration and require to include specified vitamins and nutrients, including infant formulas intended for low birth weight infants. The FDA permits does not restrict the use of cow’s milk-based infant formula for premature or low birth weight infants. Plaintiff’s contention that cow’s milk-based infant formula should never be given to premature infants is not supported by the FDA.

5. The factual background regarding the Plaintiff-minor's birth, diagnosis and injuries are limited to four paragraphs in the Complaint.

6. Plaintiffs aver that M.E. was born prematurely on September 28, 2007 and that "upon information and belief was fed Similac and/or Enfamil cow's milk-based products by staff at Pennsylvania Hospital from shortly after his birth." *Id.*, ¶¶ 11-12.

7. Plaintiffs further allege that "upon information and belief" M.E. developed NEC shortly after first ingesting the Defendant manufacturers' products. *Id.*, ¶ 13.

8. Plaintiffs generally allege that M.E. "suffered injuries and has continued to suffer long-term health effects," with no specific description of those alleged injuries or long-term health effects. *Id.*, ¶ 14.

9. Moving Defendants Preliminarily Object to Plaintiffs' Complaint for the reasons stated below and as more fully set forth in the accompanying Memorandum of Law, which is incorporated herein by reference.

II. ARGUMENT

A. DEMURRER TO COUNT VI: FAILURE TO WARN

10. Plaintiffs allege in Count VI of the Complaint that Moving Defendants, "as purchaser, supplier, and/or distributor of the products at issue in the litigation" owed Plaintiffs and the public a duty to provide products that were free of unreasonable risk of harm.

11. Plaintiffs' theory against Moving Defendants is that they were aware cow's milk-based products made by the Defendant Manufacturers cause NEC in premature and low birth weight infants and negligently failed to warn the parents of those infants of this danger.

12. In support of this theory, Plaintiffs cite to five studies comparing cow's milk-based products to breast milk, a Surgeon General report on the subject, and a statement by the American Academy of Pediatrics. *See* Exhibit "A," ¶¶ 17-23.

13. Taking these facts as pleaded by Plaintiffs as true, Plaintiffs have failed to state a claim for negligent failure to warn against Moving Defendants as they have failed to demonstrate the product in question is indeed unreasonably dangerous.

14. Further, to the extent the product at issue was provided in the context of medical care, rather than commerce, there can be no claim against Moving Defendants for a product-liability based theory of failure to warn.

15. "Pennsylvania has adopted the Restatement (Second) of Torts in cases involving a claim of negligent failure to warn." *Dauphin Deposit Bank & Trust Co. v. Toyota Motor Corp.*, 596 A.2d 845, 850 (Pa. Super. 1991). Section 388 governs this cause of action, and provides:

One who supplies directly or through a third person a chattel for another to use is subject to liability to those whom the supplier should expect to use the chattel with the consent of the other or to be endangered by its probable use, for physical harm caused by the use of the chattel in the manner for which and by a person for whose use it is supplied, if the supplier

(a) knows or has reason to know that the chattel is or is likely to be dangerous for the use for which it is supplied, and

(b) has no reason to believe that those for whose use the chattel is supplied will realize its dangerous condition, and

(c) fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be dangerous.

Restatement (Second) of Torts § 388.

16. "The threshold inquiry in all products liability cases is whether there is a defect which rendered the product unreasonably dangerous." *Weiner v. American Honda Motor Co., Inc.*, 718 A.2d 305, 307 (Pa. Super. 1998).

17. “A product is defective when it is not safe for its intended use, i.e., the product left the supplier's control lacking any element necessary to make it safe for its intended use.” *Id.* At 308.

18. Based on the foregoing, Plaintiffs must aver sufficient facts demonstrating the Defendant Manufacturers’ products are unreasonably dangerous for their intended use, triggering Moving Defendants’ duty to warn.

19. Although Plaintiffs cite in their Complaint to research studies relating to the purported risks of cow’s milk-based products in premature infants, the studies demonstrate only, assuming the facts as true as stated by Plaintiffs, that premature infants are at high risk of NEC, and that feeding such infants with breast milk may be better at reducing the risk of NEC than cow’s milk-based alternatives. *See* Exhibit “A,” ¶¶ 17-23.

20. At the outset, Plaintiffs appropriately acknowledge that “[p]reterm and low-birth-weight infants are *especially susceptible to NEC*.” *See* Exhibit “A” at ¶ 16 (emphasis added). Following this, Plaintiffs make the core claim of their Complaint – that cow’s milk-based feeding products cause NEC in preterm and low birth weight infants – and that “[e]xtensive scientific research, including numerous randomized controlled trials” confirm this claim. *Id.* However, reviewing the portions of the research and trials cited by Plaintiffs in their Complaint belie their core claim.

21. The first study cited by Plaintiffs states, according to the Complaint, that “NEC was six to ten times *more common* in exclusively cow’s milk formula-fed babies than in exclusively breast milk-fed babies and three times *more common* in babies who received a combination of formula and breast milk.” *Id.* at ¶ 17 (emphasis added). To say that NEC is more common in infants fed cow’s milk-based products than those fed breast milk is to say that NEC **still occurs in infants**

fed exclusively breast milk, but only at a lower rate. Thus, Plaintiffs' first study does not state cow's milk-based feeding products causes NEC.

22. As averred in the Complaint, the second study cited by Plaintiffs states that "preterm babies fed an exclusive breast milk-based diet were 90% less likely to develop surgical NEC compared to preterm babies fed a diet that included some cow's milk-based products." *Id.* at ¶ 18. To state that preterm infants fed only breast milk are **less likely** to develop a form of NEC is to admit that NEC still develops in preterm infants **regardless of the diet**. Thus, Plaintiffs' second study likewise does not state that cow's milk-based feeding products cause NEC.

23. The third study cited by Plaintiffs concluded, per the Complaint, "fortification of breast milk with a cow's milk-based fortifier resulted in a 4.2-fold increased risk of NEC and a 5.1-fold increased risk of surgical NEC or death compared to fortification with a breast milk-based fortifier." *Id.* at ¶ 19. What the study does not state, as alleged in the Complaint, is that cow's milk-based fortifiers cause NEC.

24. The Surgeon General report cited by Plaintiffs is alleged in the Complaint to reiterate the principle made in the prior three studies and states that "formula feeding is associated with *higher rates*" of NEC in preterm infants and that "premature infants who are not breastfed are 138% more likely to develop NEC." *Id.* at ¶ 20 (emphasis added). If cow's milk-based formula caused NEC as Plaintiffs aver, one might expect the Surgeon General report to so state. Instead, the Surgeon General report, as described in Plaintiffs' Complaint at ¶ 20, makes the same acknowledgment as Plaintiffs – that preterm infants are highly susceptible to NEC regardless of their diet, and that NEC occurs in different rates in preterm infants fed cow's milk-based products and breast milk. The report does not state that the former causes NEC.

25. According to the Complaint, the American Academy of Pediatrics makes a nearly identical statement to the Surgeon General report. *Id.* at ¶ 21. The Academy makes a recommendation that “all premature infants should be fed either their mother’s milk or, if their mother’s milk is unavailable, pasteurized donor milk,” which recommendation is alleged to be related in part to “lower rates... of NEC.” *Id.* This statement acknowledges that NEC still occurs in preterm infants fed only breast milk, but simply at a lower rate. According to the Complaint, the Academy does not claim that cow’s milk-based feeding products cause NEC.

26. The fourth and fifth studies cited by Plaintiffs in their Complaint provide similar information. As alleged in the Complaint, a study “found that premature and low-birth-weight infants fed an exclusive breast-milk-based diet suffered NEC only 3% of the time while premature and low-birth-weight infants receiving cow’s milk-based formula suffered NEC 21% of the time.” In another study, as alleged in the Complaint, “babies given exclusively breast milk products suffered NEC 5% of the time,” whereas “babies given cow’s milk products suffered NEC 17% of the time.” *Id.* at ¶ 22-23. Once again, these studies, based on the allegations in Plaintiffs’ Complaint, do not state that cow’s milk-based formula causes NEC.

27. Thus, Plaintiffs have failed to state a claim for negligent failure to warn against Moving Defendants as they have failed to state facts to establish that cow’s milk-based infant formula is unreasonably dangerous for its intended purpose.

28. Further, assuming *arguendo* that the Defendant Manufacturers’ cow’s milk-based feeding products can be seen as unreasonably dangerous for their intended use as opposed to simply being a less effective alternative to breast milk products, Moving Defendants still had no duty to warn of the nature of cow’s milk-based products under § 388 because medical providers are not “supplying” a product to a patient within the stream of commerce.

29. Plaintiffs' failure to warn claim is similarly precluded to the extent that Plaintiffs are alleging that Defendants, in providing medical care to Plaintiff-minor, failed to obtain Plaintiff-parent's consent to the use of cow's milk-based products and failed to warn of the purported risks and alternatives of such products.

30. The sole basis upon which Plaintiffs can proceed against Moving Defendants for "failure to warn" in the context of providing medical care is to assert such a claim under a theory of failure to obtain informed consent.

31. Claims for informed consent in medical malpractice actions are governed by the Medical Care Availability and Reduction of Error Act, which provides as follows:

(a) **Duty of Physicians.**--Except in emergencies, a physician owes a duty to a patient to obtain the informed consent of the patient or the patient's authorized representative prior to conducting the following procedures:

(1) Performing surgery, including the related administration of anesthesia.

(2) Administering radiation or chemotherapy.

(3) Administering a blood transfusion.

(4) Inserting a surgical device or appliance.

(5) Administering an experimental medication, using an experimental device or using an approved medication or device in an experimental manner.

(b) Description of procedure.--Consent is informed if the patient has been given a description of a procedure set forth in subsection (a) and the risks and alternatives that a reasonably prudent patient would require to make an informed decision as to that procedure. The physician shall be entitled to present evidence of the description of that procedure and those risks and alternatives that a physician acting in accordance with accepted standards of medical practice would provide.

40 P.S. §1303.504 (emphasis added).

32. Since the use of infant formula in feeding premature infants is not a “procedure,” there is no basis for Plaintiffs to contend that Plaintiff-parent’s consent was required for the use of infant formula to feed her infant, including warning her of the risks or alternatives of same.

33. Further, the informed consent statute only applies to physicians, not hospitals, in the context of medical procedures. *See Morgan v. MacPhail*, 550 Pa. 202, 205 (1997).

34. Thus, a hospital cannot be held liable for a physician’s failure to obtain proper informed consent. *Valles v. Albert Einstein Medical Center*, 805 A.2d 1232 (2002).

B. DEMURRER TO COUNT VII: CORPORATE LIABILITY OF HEALTH CARE PROVIDER

35. In *Thompson v. Nason Hospital*, 591 A.2d 703, 708 (Pa. 1991), the Pennsylvania Supreme Court recognized the doctrine of corporate liability, holding that a hospital may be found directly liable for negligence if it fails to meet *any* of the following four duties: (1) a duty to use reasonable care in the maintenance of safe and adequate facilities and equipment; (2) a duty to select and retain only competent physicians; (3) a duty to oversee all persons who practice medicine within its walls as to patient care; and (4) a duty to formulate, adopt and enforce adequate rules and policies to ensure quality care for patients.

36. Plaintiffs’ corporate liability claim fails based on the same rationale as the claim for failure to warn, since both claims are based on the alleged failure to provide warnings to patients related to the use of cow’s milk-based infant formula.

37. Infant formula is regulated by the FDA, and there is no legal restriction on the use of cow’s milk-based products for feeding of premature infants.

38. Indeed, the Infant Formula Act expressly acknowledges that it is permissible to provide cow’s-milk based products to low birth weight infants.

39. Further, as discussed above, Plaintiffs cannot demonstrate that cow's milk-based formula is an unreasonably dangerous product.

40. Thus, there is no legal basis to contend that Moving Defendants can be held liable pursuant to a theory of corporate liability for failing to prevent the use of cow's milk-based products in the feeding of premature infants in the hospital.

41. Additionally, Courts considering the application of the duties set forth in *Thompson* have insisted on more than a simple finding of a negligent act by someone for whom the hospital is purportedly responsible. *Edwards v. Brandywine Hospital*, 652 A.2d 1382 (Pa. Super. 1995).

42. In considering whether the plaintiff could sustain corporate negligence claims based on these allegations, the *Edwards* court analyzed the Thompson decision and delineated the standards required to sustain such a claim:

The *Thompson* theory of corporate liability **will not be triggered every time something goes wrong in a hospital which harms a patient** . . . To establish corporate negligence, a plaintiff must show more than an act of negligence by an individual for whom the hospital is responsible. Rather, Thompson requires a plaintiff to show that the hospital itself is breaching a duty and is somehow substandard...*Thompson* contemplates a kind of 'systemic negligence'...

Id. at 1386-87 (citations omitted and emphasis added).

43. Thus, a hospital may not be held liable via corporate negligence simply based on the alleged negligence of an individual health care provider.

44. Accordingly, even if Plaintiffs could establish that the use of cow's milk-based infant formula was a breach of the standard of care by unidentified health care providers based on the specific circumstances of the Plaintiff-minor's case herein, which has not been pleaded by Plaintiffs considering the paucity of the allegations in the Complaint, such evidence cannot support a finding of corporate liability.

45. Additionally, even assuming Plaintiffs had a viable corporate negligence claim against Pennsylvania Hospital, any such claim is precluded against the Trustees of the University of Pennsylvania since it is not a hospital.

46. The *Thompson* holding has been extended to HMO's and nursing home facilities, where it was determined that such entities performed similar functions as hospitals. *See Shannon v. Health America Pennsylvania, Inc.*, 718 A.2d 828 (Pa. Super. 1998); *Scampone v. Highland Park Care Center, LLC*, 57 A.3d 582 (Pa. 2012).

47. However, courts have routinely refused to extend the *Thompson* holding past such institutions to cover other entities, such as medical clinics and physician practice groups. *See Sutherland v. Monongahela Valley Hospital*, 856 A.2d 55, 62 (Pa. Super. 2004); *Dowhouer v. Judson*, 45 Pa. D. & C.4th 172, 180 (Pa.Com.Pl. 2000); *Brewer v. Geisinger Clinic, Inc.*, 45 Pa. D. & C.4th 215, 223 (Pa.Com.Pl. 2000); *Dibble v. Penn State Geisinger Clinic, Inc.*, 42 Pa. D. & C.4th 225 (Pa.Com.Pl. 1999); *Davis v. Gish*, 5 Pa. D. & C.5th 154, 159 (Pa.Com.Pl. 2007).

48. There is no legal basis for holding that the purported corporate parent of a hospital, such as the Trustees of the University of Pennsylvania, can be held liable under a theory of corporate negligence.

49. Indeed, the *Scampone* Court cautioned that the trial court should ensure that “multiple entities are not exposed to liability for breach of the same non-delegable duties.” 57 A.2d at 606-07.

C. MOTION TO STRIKE PLAINTIFFS' COMPLAINT FOR INSUFFICIENT SPECIFICITY AS TO THE FACTS AND ALLEGED INJURIES

50. Pursuant to Pa.R.C.P. 1028(a)(3), a party may file preliminary objections in the nature of a motion to strike for insufficient specificity in a pleading.

51. A plaintiff's Complaint is required to provide a defendant with notice of what the plaintiff's claims are and the grounds upon which they rest, and the complaint must also formulate the issues by summarizing the facts essential to support the claims. *Alpha Tau Omega Fraternity v. The University of Pennsylvania*, 464 A.2d 1349, 1352 (Pa. Super. 1983) (*citations omitted*).

52. Pennsylvania Rule of Civil Procedure 1019(a) provides that "the material facts on which a cause of action or defense is based shall be stated in a concise and summary form." Pa.R.C.P. 1019(a). As the Superior Court has noted,

Rule 1019(a) requires fact pleading. The purpose of 1019(a) is to require the pleader to disclose the material facts sufficient to enable the adverse party to prepare his case. **A complaint therefore must do more than give the defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests. It should formulate the issues by fully summarizing the material facts. Material facts are ultimate facts, i.e., those facts essential to support the claim. Evidence from which such facts may be inferred not only need not but should not be alleged. Allegations will withstand challenge under 1019(a) if (1) they contain averments of all of the facts a plaintiff will eventually have to prove in order to recover, and (2) they are sufficiently specific so as to enable defendant to prepare his defense.**

Baker v. Rangos, 324 A.2d 498, 505-506 (Pa. Super. 1974) (*citations and internal quotations omitted*)(emphasis added).

53. Further, it is well established that, with regard to the description of injuries sustained by a plaintiff, the Complaint must be stated with sufficient particularity to put the defendant on notice of evidence that may be produced at trial. *Kelly v. Martino*, 99 A.2d 901 (Pa. 1953). **A plaintiff's Complaint must set forth the extent, nature, location and duration of the injuries suffered, and injuries that are permanent should be stated specifically.** *Miller v. Perrige*, 71 Pa. D. & C.2d 476, 479–80 (Pa. Com. Pl. 1975). *See, also, Kopan v. Hawk*, 14 Pa. D. & C.2d 713, 714 (Pa. Com. Pl. 1958) ("A catchall averment of "other injuries" is nothing more than a generalized averment under which any injuries whatever could be proved at the trial. Defendant would have no knowledge in advance of the trial of what they are.")

54. Plaintiffs' Complaint is woefully deficient with regard to the specificity of the allegations of the relevant facts and injuries at issue in this case.

55. Plaintiffs' description of the material facts relating to the minor's care and treatment, diagnosis and injuries is limited to four paragraphs, which are utterly insufficient to enable defendants to prepare their defenses. *See* Exhibit "A," ¶¶ 11-14.

56. Plaintiffs aver that the minor was born prematurely but do not identify the gestational age at which the child was born or his birth weight. Plaintiffs' allegation that "upon information and belief," the minor was fed Similac and/or Enfamil shortly after his birth (*Id.* at ¶ 12) does not comply with the fact-pleading requirements of Rule 1019(a), since such allegations do not provide defendants with appropriate notice of the facts as to whether the minor actually ingested cow's milk-based products.

57. Further, plaintiffs have failed to identify which of the numerous products sold by Abbott and Mead Johnson under the Similac and Enfamil brand names were ingested by the minor. *Id.* at ¶¶ 37-38.

58. Plaintiffs' Complaint further fails to provide a description of the material facts as to the period of time in which such products were ingested, when the minor was allegedly diagnosed with NEC and what treatment was provided for that condition.

59. The Complaint further fails to state the nature of the injuries and "long-term health effects" that are alleged to have resulted from the diagnosis of NEC.

60. Plaintiffs' damages claim is not stated with particularity, is amorphous, vague, and open-ended. Pursuant to Pennsylvania pleading requirements, Moving Defendants should not be compelled to defend a claim for which the statement of injury is unspecified and subject to change.

61. These omissions are fatal defects in Plaintiff's Complaint. Therefore, Plaintiffs' Complaint should be stricken in its entirety.

D. MOTION TO STRIKE PLAINTIFFS' CLAIMS FOR PUNITIVE DAMAGES

62. In the *Ad Damnum* clauses of Counts VI and VII of the Complaint, Plaintiffs make baseless accusations that Moving Defendants engaged in oppressive, reckless, malicious and/or fraudulent conduct that allegedly justify an award of punitive damages. *See* Exhibit "A," pp. 38, 46.

63. However, the Complaint contains no specific allegations of conduct that would permit recovery of punitive damages as to Moving Defendants.

64. Rather, Plaintiffs merely allege that "upon information and belief" M.E. may have been given a cow's milk-based infant formula following birth, absent any context to indicate that such an action was inappropriate based on the specific issues involved in M.E.'s medical care and condition following birth.

65. For example, the Complaint gives no indication of whether Plaintiff-parent refused or was unable to provide breast milk and provides no information as to discussions between her and any health care providers regarding the purported use of cow's milk-based products.

66. Plaintiff's allegations of oppressive, malicious and similar conduct must be rejected as mere boilerplate. As discussed above, the FDA specifically approves the use of infant formula in care of low birth weight infants, with no restriction as to the use of cow's milk-based products for such infants.

67. Indeed, the fact that Plaintiffs have filed numerous lawsuits against at least five hospitals in Philadelphia based on identical claims belies the contention that Moving Defendants

engaged in outrageous or malicious conduct in allegedly feeding the Plaintiff-minor with cow's milk-based infant formula.

68. Absent specific factual allegations to justify the claim that the use of infant formula in M.E.'s case was extreme and outrageous, there is no basis for an award of punitive damages in this case.

69. Merely contending that punitive damages should be awarded with no supporting factual justification requires dismissal of the claim.

70. Since the purpose of punitive damages is not compensation of a plaintiff but punishment of the defendant and deterrence, punitive damages can be awarded only for conduct involving some element of outrage. *Hutchinson v. Luddy*, 582 Pa. 114, 870 A.2d 766 (2005). For that reason, Pennsylvania Supreme Court decisions establish that "punitive damages are an 'extreme remedy' available in only the most exceptional matters." *Wagner v. Onofrey*, 2006 Pa. Dist. & Cnty. Dec. LEXIS 333, *11 (Pa. Com. Pl. 2006) (citing *Phillips v. Cricket Lighters*, 584 Pa. 179, 188, 883 A.2d 439, 445 (2005)). "In fact, punitive damages are specifically designed to heap an additional punishment on a defendant who is found to have acted in a fashion which is particularly egregious." *Wagner* at *12.

71. Punitive damages may not be awarded for misconduct that constitutes ordinary negligence such as inadvertence, mistake and errors of judgment. *Martin v. Johns-Manville Corp.*, 494 A.2d 1088, 1097 (Pa. 1985); *McDaniel v. Merck, Sharp & Dohme*, 533 A.2d 436, 437 (Pa. Super. 1987). An award of punitive damages must be supported by evidence of conduct more serious than the mere commission of the underlying tort. *Allstate Ins. Co. v. A.M. Pugh Assoc., Inc.*, 604 F. Supp. 85, 99 (M.D. Pa. 1984).

72. Specifically, with regard to punitive damages in the context of claims against health care providers, the Medical Care and Reduction of Error (MCARE) Act permits punitive damages only to be awarded as follows:

- (a) Award. -- Punitive damages may be awarded for conduct that is the result of the health care provider's willful or wanton conduct or reckless indifference to the rights of others. In assessing punitive damages, the trier of fact can properly consider the character of the health care provider's act, the nature and extent of the harm to the patient that the health care provider caused or intended to cause and the wealth of the health care provider.
- (b) Gross Negligence. -- A showing of gross negligence is insufficient to support an award of punitive damages.

40 P.S. §1303.505.

73. The Supreme Court has made clear that when assessing the propriety of the imposition of punitive damages, "the state of mind of the actor is vital. The act or failure to act, must be intentional, reckless or malicious." *Hutchinson, supra* at 770. An appreciation of the risk is a necessary element of the mental state required for the imposition of punitive damages. *Id.* at 772.

74. Thus, "a punitive damages claim must be supported by evidence sufficient to establish that (1) a defendant had a subjective appreciation of the risk of harm to which the plaintiff was exposed and that (2) he acted, or failed to act, as the case may be, in conscious disregard of that risk." *Id.*

75. Since professional negligence actions involve allegations that health care professionals deviated from the governing standard of care, punitive damages are generally not recoverable in malpractice actions unless the medical provider's deviation from the applicable standard of care is so egregious as to evince a conscious or reckless disregard of a patent risk of harm to the patient. *Wagner, supra.*

76. Where the facts as averred show nothing more than negligence, a lapse in judgment, or mere inadvertence, courts in Pennsylvania have dismissed pleas and claims for punitive damages, often at the pleadings stage of litigation and even if the complaint alleged severe injuries or death. *See, e.g., Brownawell v. Bryan*, 40 Pa. D. & C.3d 604, 606 (Pa. Com. Pl. 1985) (dismissing punitive damages claim where a plaintiff alleged that a physician negligently performed a spinal fusion surgery that left the plaintiff with severe neurological defects, and noting that “**the mere pleading of outrageous conduct** does not, of course, satisfy the requirement stating facts which, if proven, would form a basis for a jury concluding that the conduct was such that an award of punitive damages was warranted.”) (emphasis added); *Wagner, supra* at *11 (contentions that physician failed to prescribe antibiotics, order certain tests or request an infectious disease consult constituted “nothing more than ordinary negligence and are insufficient to support an award of punitive damages.”); *McCardle v. Aldinger*, 5 Pa. D. & C.4th 421, 428 (Pa. Com. Pl. 1996) (sustaining preliminary objections and dismissing claim for punitive damages where the plaintiff alleged negligence in the prenatal care of her child that led to the child was stillborn and holding that “[i]t is not the outcome of the alleged negligence that is of consideration, but rather the alleged conduct of defendants that is at issue.”); *Flurer v. Pocono Medical Ctr.*, 15 Pa. D. & C.4th 645, 670 (Pa. Com. Pl. 1992) (sustaining preliminary objections and finding that plaintiffs were not “capable of pleading the requisite behavior” for an award of punitive damages where a hospital allegedly failed to properly utilize a fetal monitor on a pregnant woman who was involved in a serious car accident and thereafter delivered a stillborn child).

77. Conversely, punitive damages have been reserved for those situations that are truly egregious and utterly outrageous, and typically involve aggravating or other factors that evince a particularly reckless mind or evil motive. *See, e.g., Medvecz v. Choi*, 569 F.2d 1221, 1227-30 (3rd

Cir. 1987) (anesthesiologist who abandoned patient on operating room table and left room for a lunch break without securing a suitable replacement could be liable for punitive damages to patient who suffered irreversible paralysis from anesthesia complication that developed during his absence); *Hoffman v. Memorial Osteopathic Hospital*, 492 A.2d 1382, 386-87 (Pa. Super. 1985) (evidence that emergency room physician allowed Guillain-Barre Syndrome patient suffering from neurological paralysis to remain crying and immobile on floor for two hours as physician repeatedly stepped over patient was sufficient to support punitive damages claim); *Guernsey v. County Living Personal Care Home, Inc.*, 2006 U.S. Dist. LEXIS 31450, 2006 WL 1412765 (M.D. Pa. 2006) (punitive damages recoverable from nursing home officials who allowed resident to have access to room of 86-year old Alzheimer's patient where he repeatedly raped her, since nursing home was aware of resident's prior criminal convictions for sex registration as a sexual offender under Megan's Law, and his prior instances of grabbing and kissing staff); *Lawrence v. Kunkle*, 75 D. & C. 4th 370 (Pa. Com. Pl. 2005) (patient could maintain punitive damages claim against physician who refused to perform emergency surgery because patient did not have medical insurance even though physician knew that patient would likely suffer permanent neurologic and functional deficits if surgery was delayed).

78. The facts underlying Plaintiffs' bare assertions of reckless, outrageous or similar behavior do not even remotely meet the requisite standard under Pennsylvania law that would permit an award of punitive damages.

79. Additionally, pursuant to § 505(c) of the MCARE Act, punitive damages are specifically restricted in claims involving vicarious liability:

(c) Vicarious liability. -- Punitive damages shall not be awarded against a healthcare provider who is only vicariously liable for the actions of its agent that caused the injury unless it can be shown by a preponderance of the evidence that

the party knew of and allowed the conduct of its agent that resulted in an award of punitive damages.

40 P.S. §1303.505(c).

80. Plaintiffs allege in this action that unidentified “staff” fed M.E. Similac and/or Enfamil at Pennsylvania Hospital shortly after his birth and failed to warn Plaintiff-parent of the alleged risks of such products. See Exhibit “A,” ¶ 12.

81. Even if such actions were claimed to be egregious or malicious such that punitive damages were permissible, which is denied for the reasons stated above, Plaintiffs must allege facts to establish that Moving Defendants had actual knowledge of the alleged wrongful conduct and nevertheless allowed it. *See Zazzera v. Roche*, 54 D. & C. 4th 225, 238 (Pa. Com. Pl. 2001); *Dean Witter Reynolds, Inc. v. Genteel*, 499 A.2d 637 (Pa. Super. 1985).

82. In this matter, Plaintiffs have failed to plead any facts to suggest that Moving Defendants were aware of any alleged misconduct by any individual alleged to be an agent and allowed such conduct to continue.

83. For all these reasons, Plaintiffs’ demand for punitive damages must be stricken with prejudice as to Moving Defendants, along with all allegations of reckless and similar conduct.

E. MOTION TO DISMISS PLAINTIFF-PARENT’S CLAIMS

84. Plaintiff-parent seeks to recover damages in her own right and as the parent and natural guardian of M.E.

85. Plaintiffs’ Complaint includes allegations in each count asserted as to Moving Defendants in which it is averred that Plaintiff-parent “suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly altered by the Injured Infant’s injuries.” *See* Exhibit “A,” ¶¶ 126, 139 and 147.

86. However, no specific cause of action is asserted as to any damages sought by behalf of Plaintiff-parent, who is not alleged in the Complaint to have suffered any physical injuries as a result of the alleged negligent conduct of Moving Defendants. For this reason, Plaintiff-parent's claim should be dismissed.

87. Further, even if Plaintiff-parent had properly articulated a cause of action in the Complaint to allow her to recover damages in her own right, the Complaint should be stricken pursuant to Pa.R.C.P. 1020(b), which provides as follows:

If persons join as plaintiffs under Rules 2228, 2229(a) or (e), the complaint shall state the cause of action, any special damage, and the demand for relief of each plaintiff in a separate count, preceded by a heading naming the parties to the causes of action therein set forth.

88. Accordingly, it is improper for Plaintiffs to plead in a single count claims on behalf of both the Plaintiff-minor and the Plaintiff-parent, as was done in the Complaint filed herein. Claims on behalf of each of the Plaintiffs must be set forth in separate counts of the Complaint, specifically identifying the cause of action asserted and relief sought in each count.

89. Additionally, although the statute of limitations for claims asserted on behalf of minors are tolled until the age of majority, Plaintiff-parent's claims were not similarly tolled and were required to have been brought within two years of the alleged injury. *See Hathi v. Krewstown Park Apts*, 561 A.2d 1261 (Pa. Super. 1989); 42 Pa.C.S. § 5524.

90. Plaintiffs allege that M.E. was born on September 28, 2007, was fed the Defendant manufacturers' products shortly after his birth, and developed NEC shortly thereafter. *See Exhibit "A,"* ¶¶ 11-13.

91. Thus, since the Complaint herein was filed on March 24, 2022, Plaintiff-parent's claims herein are clearly time-barred based on the applicable statute of limitations.

F. MOTION TO STRIKE PLAINTIFFS' COMPLAINT FOR FAILURE TO COMPLY WITH Pa.R.C.P. 1024

92. Pennsylvania Rule of Civil Procedure 1024(a) requires verification of every pleading containing a factual averment based upon the signer's personal knowledge or information and belief.

93. Rule 1024(c) requires that the verification be made by one or more of the parties filing the pleading.

94. In this case, Plaintiffs' counsel signed the verification for the Complaint, in violation of Rule 1024. *See* Exhibit "A."

95. Accordingly, the Complaint should be stricken for lack of an appropriate verification.

WHEREFORE, Defendants The Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital and The Trustees of the University of Pennsylvania d/b/a Penn Medicine respectfully request that this Honorable Court sustain the instant Preliminary Objections and enter the attached proposed Order.

BURNS WHITE LLC

BY: 

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Alice Stills, on her own behalf and as Parent
and Natural Guardian of M.E., a minor

Plaintiffs

v.

MEAD JOHNSON & COMPANY, LLC, et
al.

Defendants.

COURT OF COMMON PLEAS
PHILADELPHIA COUNTY

CIVIL DIVISION

MARCH TERM, 2022
NO. 2617

**MEMORANDUM OF LAW IN SUPPORT OF PRELIMINARY OBJECTIONS OF
DEFENDANTS THE PENNSYLVANIA HOSPITAL OF THE UNIVERSITY OF
PENNSYLVANIA HEALTH SYSTEM AND THE TRUSTEES OF THE UNIVERSITY
OF PENNSYLVANIA TO PLAINTIFFS' COMPLAINT**

I. MATTER BEFORE THE COURT

Preliminary Objections of Defendants The Pennsylvania Hospital of the University of Pennsylvania Health System (“Pennsylvania Hospital”) and The Trustees of the University of Pennsylvania to Plaintiffs’ Complaint.

While patently obvious that Plaintiffs’ Complaint must be dismissed for clear and important violations of the procedural requirements governing pleadings and verification of the accuracy of the factual averments of the Complaint (there are not separate counts identified for the causes of action of each of the Plaintiffs attempts to allege), most of which are averred “upon

information and belief,” the substance of Plaintiffs’ allegations do not support any legally recognized cause of action against Moving Defendants, under Pennsylvania law. Our procedural rules do not permit a plaintiff to simply identify allegedly tortious conduct by a defendant without pleading the necessary facts to satisfy the elements of the tortious conduct.

Here, Plaintiffs plead that Moving Defendants permitted Co-Defendants’ cow’s milk-based infant formula to be fed to prematurely born infants, which allegedly caused those infants to develop necrotizing enterocolitis (“NEC”). Plaintiffs then plead themselves out of Court by attempting to support a “failure to warn” claim by referencing various articles that, as pleaded and for purposes of these Preliminary Objections accepted as true, do not support the contention that cow’s milk-based infant formulas cause NEC. Thus, distinct from the Complaint’s procedural shortcomings, Plaintiffs have failed to plead facts that support the “failure to warn” and corporate liability causes of action that they attempt to assert against Moving Defendants. It is further noteworthy that there is no viable “failure to warn” cause of action that is recognized under Pennsylvania law against Moving Defendants, as explained in this submission by Moving Defendants.

II. STATEMENT OF QUESTIONS PRESENTED

1. Whether this Honorable Court should dismiss Count VI of Plaintiffs’ Complaint “Failure to Warn” cause of action with prejudice because Plaintiffs’ Complaint does not support the claim that cow’s milk-based products are unreasonably dangerous and Moving Defendants cannot be held liable for negligent failure to warn on the basis that they are a supplier of such products?

Suggested answer in the affirmative.

2. Whether this Honorable Court should dismiss Count VI of Plaintiffs' Complaint "Failure to Warn" cause of action with prejudice because it improperly alleges that Moving Defendants were required to obtain Plaintiff-parent's informed consent to use of cow's milk-based products for feeding of Plaintiff-minor and warn her of the risks and/or alternatives of same?

Suggested answer in the affirmative.

3. Whether this Honorable Court should dismiss Count VII of Plaintiffs' Complaint "Corporate Negligence" cause of action with prejudice because Moving Defendants cannot be held liable on such a theory for a product which is regulated by the FDA and which is not precluded for use in premature or low birth weight infants, and where a hospital cannot be held liable for corporate negligence based on the alleged negligence of an individual health care provider?

Suggested answer in the affirmative.

4. Whether this Honorable Court should dismiss Count VII of Plaintiffs' Complaint "Corporate Negligence" cause of action with prejudice as to the Trustees of the University of Pennsylvania since it is not a hospital and because corporate negligence duties are non-delegable?

Suggested answer in the affirmative.

5. Whether this Honorable Court should strike Plaintiffs' Complaint in its entirety for insufficient specificity of the facts and alleged injuries?

Suggested answer in the affirmative.

6. Whether this Honorable Court should strike Plaintiffs' claims for punitive damages as to Moving Defendants because the Complaint fails to plead facts providing a basis for an award of punitive damages?

Suggested answer in the affirmative.

7. Whether this Honorable Court should strike Plaintiff-parent's claims for failure to state a cause of action, and for failure to plead separate causes of action pursuant to Pa.R.C.P. 1020 and based on the applicable statute of limitations?

Suggested answer in the affirmative.

8. Whether this Honorable Court should strike Plaintiffs' Complaint for failure to provide a client verification as required by Pa.R.C.P. 1024?

Suggested answer in the affirmative.

III. INTRODUCTION AND FACTUAL BACKGROUND

Plaintiffs have filed a slew of essentially identical lawsuits against Pennsylvania Hospital and other hospitals in Philadelphia based on claims relating to alleged ingestion of cow's milk-based products by premature infants in the hospital following their birth.¹ Plaintiffs allege that the Plaintiff-minors, including M.E., were diagnosed with necrotizing enterocolitis (NEC), a gastrointestinal disorder that premature infants are at increased risk to develop. *See* Plaintiffs' Complaint, attached as Exhibit "A" at ¶ 13. Plaintiffs aver that premature infants fed with their mother's breast milk or donor breast milk are at decreased risk of developing NEC as compared with infants given cow's milk-based products (infant formula). Many of the allegations of the Complaint are pleaded "upon information and belief," including the allegations that Plaintiff-minors received infant formula and that they developed NEC shortly after being fed with infant formula.

In addition to asserting product liability claims against the infant formula manufacturers Mead Johnson & Company, LLC, Mead Johnson Nutritional Company (collectively referred to as

¹ Lawsuits involving identical claims have been filed against the Hospital of the University of Pennsylvania, Temple University Hospital, Albert Einstein Medical Center and Thomas Jefferson University Hospital.

“Mead Johnson”) and Abbott Laboratories (“Abbott”)², Plaintiffs have alleged that Moving Defendants are liable based on theories of failure to warn and corporate liability. *See* Plaintiff’s Complaint, attached as Exhibit “A” at Counts VI and VII. As is discussed in detail below, Plaintiffs’ claims against Moving Defendants are legally and factually deficient.

Although Plaintiffs aver that NEC is caused by cow’s milk-based products, Plaintiffs refer in their Complaint to research studies and reports that, as alleged by Plaintiffs, indicate only that NEC is more common in premature and low birth weight infants fed with cow’s milk-based products as compared with similar infants fed with breast milk. *See* Exhibit “A,” ¶¶ 17-23. As discussed in detail *supra*, assuming the truth of the factual allegations stated in Plaintiffs’ Complaint, the research studies cited by Plaintiffs do not support the conclusion that NEC is caused by cow’s milk-based products. As such, there is no basis to contend that cow’s milk-based products are dangerous for premature infants, such that Moving Defendants had a duty to warn Plaintiff-parents of any risks or alternatives related to infant formula.

Plaintiffs’ Complaint provides scant information regarding the factual background of this case. Plaintiffs aver that M.E. was born prematurely on September 28, 2007 and that “upon information and belief was fed Similac and/or Enfamil cow’s milk-based products by staff at Pennsylvania Hospital from shortly after his birth.” *Id.*, ¶¶ 11-12. Plaintiffs further allege that “upon information and belief” M.E. developed NEC shortly after first ingesting the Defendant manufacturers’ products. *Id.*, ¶ 13. No details are provided regarding the extent of her prematurity, his birth weight, or his condition following birth other than that he developed NEC on an unidentified date. Further, no facts are provided by Plaintiffs as to any medical care M.E. received for what period of time M.E. allegedly ingested cow’s milk-based products, and which product(s)

² Mead Johnson and Abbott have been the subject of similar lawsuits in other states, including Connecticut, Illinois and California.

he allegedly ingested.³ Finally, the Complaint is silent as to the nature and extent of M.E.’s alleged injuries other than a vague reference to “long term health effects.” *Id.* ¶ 14.

Further, the Complaint does not provide any details whatsoever regarding communications between Plaintiff-parent and medical providers at Pennsylvania Hospital regarding the allegations that M.E. may have been fed with Mead Johnson and/or Abbott cow’s milk-based products in the hospital. Plaintiffs conceded in the Complaint that mothers are encouraged by their healthcare professionals to breastfeed. *Id.* ¶ 41. However, Plaintiffs do not provide any information regarding discussions between Plaintiff-parent and any health care providers at Pennsylvania Hospital related to breastfeeding and/or using cow’s milk-based products in this case, including whether or not she was encouraged to breastfeed and/or was unable or declined to do so. As noted, Plaintiffs plead that Plaintiff Minor ingested formula “on information and belief” only, and similarly plead “on information and belief” that Plaintiff Minor developed NEC as a result.

Plaintiffs further fail to disclose in their Complaint that infant formula is regulated by the United States Food and Drug Administration (FDA) and that there is no restriction on the use of cow’s milk-based products for premature infants. The federal Infant Formula Act of 1980 (“IFA”) was enacted “to assure the safety and nutrition of infant formulas.” Pub. L. No. 96-359, 94 Stat. 1190. The IFA and its implementing regulations outline the requirements that infant formula must meet, including how infant formula is made, its contents and ingredients, and the labels used on its packages. 21 U.S.C. § 350a; 21 C.F.R. §§ 106-07. The IFA provides that infant formulas may only contain “substances that are safe and suitable for use in infant formula.” 21 C.F.R. § 106.40(a). Neither the IFA nor the regulations exclude cow milk as an ingredient, and many infant formulas

³ Plaintiffs aver that Abbott sells at least seven types of products directed to preterm and/or low birth weight infants, six of which use the name Similac, and that Mead Johnson sells eight types of infant formulas using the Enfamil brand name. *Id.*, ¶¶ 37-38.

for sale include cow milk. (Exhibit “A,” ¶¶ 37-38); 21 C.F.R. § 106.3 (“infant formula” is a “food for infants by reason of its *simulation* of human milk”) (emphasis added). 21 U.S.C. § 350a; 21 C.F.R. §§ 107.50. Before selling any “new infant formula,” a manufacturer must (1) register with the FDA, and (2) submit a notice to the FDA at least 90 days before marketing such formula. The notice must also state that the formula contains the required vitamins and nutrients, as demonstrated by testing. 21 U.S.C. § 350a(b). These same FDA review procedures apply when a manufacturer makes a “major change” to an existing formula. 21 U.S.C. § 350a(c)(2)(B); 21 C.F.R. § 106.3.

Further, the FDA recognizes that certain infant formulas are intended for low birth weight babies (such as infants born prematurely) or infants with unusual medical or dietary problems. Indeed, such formulas have special review requirements. 21 U.S.C. § 350a(h); 21 C.F.R. § 107.50(a). For those formulas – known as “exempt” formulas because they may be exempted from certain requirements – the required 90-day notice must include “the label and other labeling of the infant formula, a complete quantitative formulation for the infant formula, and a detailed description of the medical conditions for which the infant formula is represented.” 21 C.F.R. § 107.50(b)(3). As with other formulas, the regulations do not exclude cow milk as an ingredient for infant formulas intended for use by an infant with a low birth weight.

Thus, since Plaintiffs do not allege that the product did not meet federal requirements, there is no basis for any claim that the product is unreasonably dangerous and/or should not be given under any circumstances to premature or low birth weight infants.

IV. ARGUMENT

A. DEMURRER TO COUNT VI: FAILURE TO WARN

1. **Moving Defendants Cannot Be Held Liable to Plaintiffs Based on a Theory of Failure to Warn Because the Infant Formula is Not Unreasonably Dangerous**

Pursuant to Pa.R.C.P. 1028(a)(4), a party may file preliminary objections to a complaint, in the nature of a demurrer, for legal insufficiency in a pleading. A court should grant a demurrer where, accepting as true all well pled facts, a legal cause of action cannot be maintained upon those facts. Pa.R.C.P. 1028(a)(4); *See also, Willet v. Pennsylvania Med. Catastrophe Loss Fund*, 702 A.2d 850, 853 (Pa. 1997).

Plaintiffs allege in Count VI of the Complaint that Moving Defendants, “as purchaser, supplier, and/or distributor of the products at issue in the litigation” owed Plaintiffs and the public a duty to provide products that were free of unreasonable risk of harm. Plaintiffs’ theory against Moving Defendants is that they were aware cow’s milk-based products manufactured by Mead Johnson and Abbott cause NEC in premature and low birth weight infants and negligently failed to warn the parents of those infants of this danger. In support of this theory, Plaintiffs cite to five studies comparing cow’s milk-based products to breast milk, a Surgeon General report on the subject, and a statement by the American Academy of Pediatrics. Taking these facts as pleaded by Plaintiffs as true, Plaintiffs have failed to state a claim for negligent failure to warn against Moving Defendants as they have failed to demonstrate the products in question are indeed unreasonably dangerous. Further, to the extent the product at issue was provided in the context of medical care, rather than commerce, there can be no claim against Moving Defendants for a product-liability based theory of failure to warn.

“Pennsylvania has adopted the Restatement (Second) of Torts in cases involving a claim of negligent failure to warn.” *Dauphin Deposit Bank & Trust Co. v. Toyota Motor Corp.*, 596 A.2d 845, 850 (Pa. Super. 1991). Section 388 governs this cause of action, and provides:

One who supplies directly or through a third person a chattel for another to use is subject to liability to those whom the supplier should expect to use the chattel with the consent of the other or to be endangered by its probable use, for physical harm caused by the use of the chattel in the manner for which and by a person for whose use it is supplied, if the supplier

- (a) knows or has reason to know that the chattel is or is likely to be dangerous for the use for which it is supplied, and
- (b) has no reason to believe that those for whose use the chattel is supplied will realize its dangerous condition, and
- (c) fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be dangerous.

Restatement (Second) of Torts § 388. To survive preliminary objections, Plaintiffs must aver sufficient facts, together with the documents and exhibits attached thereto, to make out a *prima facie* case as to all elements of the cause of action. *Northern Forests II, Inc. v. Keta Realty Co.*, 130 A.3d 19, 35 (Pa. Super. 2015).

“The threshold inquiry in all products liability cases is whether there is a defect which rendered the product unreasonably dangerous.” *Weiner v. American Honda Motor Co., Inc.*, 718 A.2d 305, 307 (Pa. Super. 1998). “A product is defective when it is not safe for its intended use, i.e., the product left the supplier's control lacking any element necessary to make it safe for its intended use.” *Id.* At 308. Whether a product is “unreasonably dangerous” is a question of law. *Id.* Based on the foregoing, Plaintiffs must aver sufficient facts demonstrating the Defendant Manufacturers’ products are unreasonably dangerous for their intended use, triggering Moving Defendants’ duty to warn. They have not done so as the studies they cite in their Complaint do not

say – based on the very allegations in the Complaint - what Plaintiffs claim they do. Therefore, Moving Defendants had no corresponding duty to warn.

At the outset, Plaintiffs appropriately acknowledge that “[p]reterm and low-birth-weight infants are *especially susceptible to NEC*.” See Exhibit “A” at ¶ 16 (emphasis added). Following this, Plaintiffs make the core claim of their Complaint – that cow’s milk-based feeding products cause NEC in preterm and low birth weight infants – and that “[e]xtensive scientific research, including numerous randomized controlled trials” confirm this claim. *Id.* Admittedly, if a product directly causes NEC in preterm and low birth weight infants, that product would certainly be dangerous. However, reviewing the portions of the research and trials cited by Plaintiffs in their Complaint belie their core claim.⁴

The first study cited by Plaintiffs states, according to the Complaint, that “NEC was six to ten times *more common* in exclusively cow’s milk formula-fed babies than in exclusively breast milk-fed babies and three times *more common* in babies who received a combination of formula and breast milk.” *Id.* at ¶ 17 (emphasis added). To say that NEC is more common in infants fed cow’s milk-based products than those fed breast milk is to say that NEC **still occurs in infants fed exclusively breast milk**, but only at a lower rate. Thus, Plaintiffs’ first study does not state cow’s milk-based feeding products causes NEC.

As averred in the Complaint, the second study cited by Plaintiffs states that “preterm babies fed an exclusive breast milk-based diet were 90% less likely to develop surgical NEC compared to preterm babies fed a diet that included some cow’s milk-based products.” *Id.* at ¶ 18. To state

⁴ To the extent Plaintiffs’ claim that Defendant Manufacturers’ cow’s milk-based products increased the risk of NEC in preterm and low-birth-weight infants, they still fail to plead sufficient facts to support this claim. The portions of the studies relied upon by Plaintiffs, taken as true at this juncture, show only that NEC can be more common in preterm and low-birth-weight infants fed cow’s milk-based products than in those fed breast or donor milk. These studies do not show the cow’s milk-based products **caused** any increase in risk. To the extent Plaintiffs’ state the studies do reflect an increased risk of NEC in the infants, this is a legal conclusion without factual basis, which is impermissible under Pa. R. Civ. P. 1019 (see discussion *supra* at p. 19).

that preterm infants fed only breast milk are **less likely** to develop a form of NEC is to admit that NEC still develops in preterm infants **regardless of the diet**. Thus, Plaintiffs' second study likewise does not state that cow's milk-based feeding products cause NEC.

The third study cited by Plaintiffs concluded, per the Complaint, "fortification of breast milk with a cow's milk-based fortifier resulted in a 4.2-fold increased risk of NEC and a 5.1-fold increased risk of surgical NEC or death compared to fortification with a breast milk-based fortifier." *Id.* at ¶ 19. As Plaintiffs admitted in the Complaint, preterm and low-weight-birth infants are especially susceptible to NEC. Put another way, **these infants are already at an increased risk of NEC regardless of their diet**. This study, as described in Plaintiffs' Complaint, reflects this in explaining different rates of risk of developing NEC when using cow's milk-based or breast milk-based fortifiers. What the study does not state, as alleged in the Complaint, is that cow's milk-based fortifiers cause NEC.

The Surgeon General report cited by Plaintiffs is alleged in the Complaint to reiterate the principle made in the prior three studies and states that "formula feeding is associated with *higher rates*" of NEC in preterm infants and that "premature infants who are not breastfed are 138% more likely to develop NEC." *Id.* at ¶ 20 (emphasis added). If cow's milk-based formula caused NEC as Plaintiffs aver, one might expect the Surgeon General report to so state. Instead, the Surgeon General report, as described in Plaintiffs' Complaint at ¶ 20, makes the same acknowledgment as Plaintiffs – that preterm infants are highly susceptible to NEC regardless of their diet, and that NEC occurs in different rates in preterm infants fed cow's milk-based products and breast milk. The report does not state that the former causes NEC.

According to the Complaint, the American Academy of Pediatrics makes a nearly identical statement to the Surgeon General report. *Id.* at ¶ 21. The Academy makes a recommendation that

“all premature infants should be fed either their mother’s milk or, if their mother’s milk is unavailable, pasteurized donor milk,” which recommendation is alleged to be related in part to “lower rates... of NEC.” *Id.* This statement acknowledges that NEC still occurs in preterm infants fed only breast milk, but simply at a lower rate. According to the Complaint, the Academy does not state that cow’s milk-based feeding products cause NEC.

The fourth and fifth studies cited by Plaintiffs in their Complaint provide similar information. As alleged in the Complaint, a study “found that premature and low-birth-weight infants fed an exclusive breast-milk-based diet suffered NEC only 3% of the time while premature and low-birth-weight infants receiving cow’s milk-based formula suffered NEC 21% of the time.” In another study, as alleged in the Complaint, “babies given exclusively breast milk products suffered NEC 5% of the time,” whereas “babies given cow’s milk products suffered NEC 17% of the time.” *Id.* at ¶ 22-23. Once again, these studies, based on the allegations in Plaintiffs’ Complaint, do not state that cow’s milk-based formula causes NEC.

Ultimately, Plaintiffs’ claim that Defendant Manufacturers’ cow’s milk-based feeding products cause NEC and are therefore unreasonably dangerous rests upon the notion that correlation equals causation. The numerous studies and reports cited by Plaintiffs in their Complaint purportedly show higher rates of NEC in preterm and low birth weight infants fed cow’s milk-based diets than those fed breast milk, but this data exists in a world where Plaintiffs admit these infants are at a high risk of developing NEC regardless of diet. All that Plaintiffs’ Complaint demonstrates, as pleaded under these facts, is that breast milk may be better at reducing that already high risk of NEC in these infants than cow’s milk-based alternatives. This proposition does not make the Defendant Manufacturers’ cow’s milk-based alternatives unreasonably dangerous within

the meaning of § 388 of the Restatement (Second) of Torts and, accordingly, does not trigger a duty to warn on the part of Moving Defendants.

2. Moving Defendants Are Not a “Supplier” and, Therefore, Cannot Be Held Liable for Negligent Failure to Warn

Assuming *arguendo* that the Defendant Manufacturers’ cow’s milk-based feeding products can be seen as dangerous for their intended use as opposed to simply being a less effective alternative to breast milk products, Moving Defendants still had no duty to warn of the nature of cow’s milk-based products under § 388 because they are not considered a supplier of cow’s milk-based feeding products. Plaintiffs cite to no caselaw in Pennsylvania holding that a hospital is considered a supplier under § 388. Indeed, extensive research into this topic turns up no prior decisions where a Pennsylvania court has found a hospital to be a supplier in a products liability case for negligent failure to warn.

To determine a hospital may be defined as supplier of products ancillary to and following medical services within the meaning of § 388 would be to impose on the hospital a duty to warn about every conceivable object a patient may encounter in a hospital, right down to the napkins available in the hospital cafeteria. Imposing such a duty does nothing to advance the purpose of products liability law, i.e. to protect consumers from dangerous products in the stream of commerce. Moving Defendants are not in the best position to determine what products are available in the market for premature and low weight birth infants. In light of this, Plaintiffs have not sufficiently pleaded that Moving Defendants are a supplier under § 388.

For the foregoing reasons, Plaintiffs have not pleaded sufficient facts to aver the Defendant Manufacturers’ products are unreasonably dangerous for their intended use and thus have not established Moving Defendants had a duty to warn. Alternatively, even if the products at issue here can be viewed as unreasonably dangerous, Plaintiffs still have failed to plead sufficient facts

that Moving Defendants are a supplier of products that are ancillary to the medical services provided to Plaintiffs. Accordingly, it is respectfully requested this Court sustain Moving Defendants' Preliminary Objections to Count VI: Failure to Warn of Plaintiffs' Complaint.

3. There is no Legal Basis for Plaintiffs to Present an Informed Consent Claim Regarding the Use of Cow's milk-based products

Plaintiffs' failure to warn claim is couched in language of product liability related to Moving Defendants' alleged duty "as a purchaser, supplier and/or distributor" to provide a product (cow's milk-based infant formula) that was free of unreasonable risk of harm to consumers (parents and their premature infants). This theory fails for the reasons stated above. However, to the extent that Plaintiffs are alleging that Moving Defendants, in providing medical care to Plaintiff-minor, failed to obtain Plaintiff-parent's consent to the use of cow's milk-based products and failed to warn of the purported risks and alternatives of such products, such a claim is also clearly precluded by Pennsylvania law.

Plaintiffs broadly allege that Moving Defendants failed to warn of the alleged dangers of cow's milk-based products and provide them with information necessary "to make an informed choice about whether to allow their baby to be fed the Defendant Manufacturers' products." *See* Exhibit "A" at ¶ 121. This purported failure to warn/inform allegedly led Plaintiff-minor to be fed a cow's milk-based product that Plaintiffs' contend caused and/or increased the risk of NEC. *Id.* at ¶ 125. The sole basis upon which Plaintiffs can proceed against Moving Defendants for "failure to warn" in the context of providing medical care is to assert such a claim under a theory of failure to obtain informed consent. Plaintiffs are impliedly asserting that Moving Defendants failed to obtain Plaintiff-parent's informed consent as to whether she should use cow's milk-based infant formula to feed her child as opposed to breastfeeding or using breast donor milk, based on the

alleged risks of cow's milk-based products. However, such a claim is not cognizable under Pennsylvania law.

Claims for informed consent in medical malpractice actions are governed by the Medical Care Availability and Reduction of Error Act, which provides as follows:

(a) **Duty of Physicians.**--Except in emergencies, a physician owes a duty to a patient to obtain the informed consent of the patient or the patient's authorized representative prior to conducting the following procedures:

- (1) Performing surgery, including the related administration of anesthesia.
- (2) Administering radiation or chemotherapy.
- (3) Administering a blood transfusion.
- (4) Inserting a surgical device or appliance.
- (5) Administering an experimental medication, using an experimental device or using an approved medication or device in an experimental manner.

(b) Description of procedure.--Consent is informed if the patient has been given a description of a procedure set forth in subsection (a) and the risks and alternatives that a reasonably prudent patient would require to make an informed decision as to that procedure. The physician shall be entitled to present evidence of the description of that procedure and those risks and alternatives that a physician acting in accordance with accepted standards of medical practice would provide.

40 P.S. §1303.504 (emphasis added).

The clear language of the statute above reveals two significant tenets. The first is that the informed consent statute does not apply to the use of infant formula in feeding premature infants, since that is not a "procedure." Thus, there is no basis for Plaintiffs to contend that Plaintiff-parent's consent was required for the use of infant formula to feed her infant, including warning her of the risks or alternatives of same. Second, the informed consent statute only applies to

physicians, not hospitals, in the context of medical procedures. *See Morgan v. MacPhail*, 550 Pa. 202, 205 (1997).

Informed consent has not been extended to any type of therapeutic treatment involving an ingestible therapeutic drug, which the court defined as “an ongoing treatment upon examination by the treating physician, where any change of condition can be diagnosed and controlled.” *Boyer v. Smith*, 345 Pa. Super. 66, 71, 497 A.2d 646, 648 (1985). The Superior Court ruled that the informed consent doctrine is premised upon the legal theory that the performance of a medical procedure without a patient's informed consent constitutes a technical assault or battery and that merely prescribing an oral medication does not involve a touching so not battery can occur and no informed consent is needed. *Id.* at 649. The same principles clearly apply to administration of infant formula to a newborn.

Further, an informed consent claim is only applicable to a physician and not the hospital and/or other health care entities. *See* 40 P.S. § 1303.504; *see also Kelly v. Methodist Hosp.*, 664 A.2d 148 (Pa. Super. 1995) (holding that generally only the physician who performs the operation on the patient has the duty of obtaining his consent for the procedure). The Pennsylvania Supreme Court has held that informed consent involves the relationship between a physician and the patient and that the failure to obtain proper informed consent is deemed a battery, and the institution plays no role in the communications involved in obtaining the same. *See Valles v. Albert Einstein Medical Center*, 805 A.2d 1232 (2002). In *Valles*, the Court decisively ruled that:

We find that a battery which results from a lack of informed consent is not the type of action that occurs within the scope of employment. In our view, a medical facility cannot maintain control over this aspect of the physician-patient relationship. Our lower courts have recognized that the duty to obtain informed consent belongs solely to the physician. (Citations omitted). Informed consent flows from the discussions each patient has with his physician, based on the facts and circumstances each case presents. We decline to interject an element of a hospital's control into this highly individualized and dynamic relationship. We agree with the

lower court that to do so would be both improvident and unworkable. Thus, we hold that as a matter of law, a medical facility lacks the control over the manner in which the physician performs his duty to obtain informed consent so as to render the facility vicariously liable.

Id., 805 A.2d at 1239 (emphasis added). The *Valles* case remains the prevailing law in Pennsylvania. Pennsylvania courts have repeatedly applied this doctrine, recognizing and acknowledging that “[i]n a claim alleging lack of informed consent, it is the conduct of the unauthorized procedure that constitutes the tort.” *Isaac v. Jameson Mem. Hosp.*, 932 A.2d 924, 929 (Pa. Super. 2007) (citing *Moure v. Raeuchle*, 604 A.2d 1003, 1008 (Pa. Super. 1992)). Further, “[g]iven the unique nature of the doctrine and its origins as a technical battery, hospitals cannot be held vicariously liable for a physician’s failure to obtain informed consent because ‘a medical facility cannot maintain control over this aspect of the physician-patient relationship.’” *Isaac*, 932 A.2d at 930. As such, it is clear that the instant cause of action cannot be sustained against Moving Defendants as a matter of law.

B. DEMURRER TO COUNT VII: CORPORATE LIABILITY OF HEALTH CARE PROVIDER

1. Moving Defendants Cannot be Held Liable for Corporate Negligence Regarding a Food Product Which is Permitted for its Intended Use Pursuant to Federal Law

In *Thompson v. Nason Hospital*, 591 A.2d 703, 708 (Pa. 1991), the Pennsylvania Supreme Court recognized the doctrine of corporate liability, holding that a hospital may be found directly liable for negligence if it fails to meet *any* of the following four duties: (1) a duty to use reasonable care in the maintenance of safe and adequate facilities and equipment; (2) a duty to select and retain only competent physicians; (3) a duty to oversee all persons who practice medicine within its walls as to patient care; and (4) a duty to formulate, adopt and enforce adequate rules and policies to ensure quality care for patients.

Plaintiffs' corporate liability claim fails based on the same rationale as the claim for failure to warn. Both claims are based on the alleged failure to provide warnings to patients related to the use of cow's milk-based infant formula. As noted above, infant formula is regulated by the FDA, and there is no legal restriction on the use of cow's milk-based products for feeding of premature infants. Indeed, the Infant Formula Act expressly acknowledges that it is permissible to provide cow's-milk based products to low birth weight infants. Further, as discussed above, Plaintiffs cannot demonstrate that cow's milk-based formula is a dangerous product. Thus, there is no legal basis to contend that Moving Defendants can be held liable pursuant to a theory of corporate liability for failing to preclude the use of cow's milk-based products in the feeding of premature infants in the hospital.

Additionally, Courts considering the application of the duties set forth in *Thompson* have insisted on more than a simple finding of a negligent act by someone for whom the hospital is purportedly responsible. *Edwards v. Brandywine Hospital*, 652 A.2d 1382 (Pa. Super. 1995). In considering whether the plaintiff could sustain corporate negligence claims based on these allegations, the court analyzed the Thompson decision and delineated the standards required to sustain such a claim:

The *Thompson* theory of corporate liability **will not be triggered every time something goes wrong in a hospital which harms a patient** . . . To establish corporate negligence, a plaintiff must show more than an act of negligence by an individual for whom the hospital is responsible. Rather, Thompson requires a plaintiff to show that the hospital itself is breaching a duty and is somehow substandard...*Thompson* contemplates a kind of 'systemic negligence'...

Id. at 1386-87 (citations omitted and emphasis added). Thus, corporate liability requires "more than individual acts of negligence." *Id.* As noted by the court in *Edwards*, this reading of the Court's opinion in *Thompson* is the only way to logically construe its holding, as hospitals are already held vicariously liable for the negligent acts of their employees and ostensible agents, while "Thompson

requires a plaintiff to show that the **hospital itself** is breaching a duty and is somehow substandard.” *Id.* at 1387; *see also MacDonald v. Chestnut Hill Hosp.*, 2005 Phila. Ct. Com. Pl. LEXIS 273, 18 (Pa. C.P. 2005) (granting nonsuit to the hospital defendant where “[t]here was no evidence that protocols were routinely ignored to the detriment of patients or that the kind of systematic negligence on the part of CHH required by the *Edwards* decision was present.”)

Thus, a hospital may not be held liable via corporate negligence simply based on the alleged negligence of an individual health care provider. Accordingly, even if Plaintiffs could establish that the use of cow’s milk-based infant formula was a breach of the standard of care by unidentified health care providers based on the specific circumstances of the Plaintiff-minor’s case herein, which has not been pleaded by Plaintiffs considering the paucity of the allegations in the Complaint, such evidence cannot support a finding of corporate liability.

For the reasons stated above, Count VII of Plaintiffs’ Complaint should be dismissed with prejudice.

2. Plaintiffs Are Precluded From Pursuing Corporate Negligence Claims as to The Trustees of the University of Pennsylvania

As noted *infra*, the Pennsylvania Supreme Court set forth certain nondelegable duties of hospitals, which if violated may support a finding of corporate negligence. The *Thompson* holding has been extended to HMO’s and nursing home facilities, where it was determined that such entities performed similar functions as hospitals. *See Shannon v. Health America Pennsylvania, Inc.*, 718 A.2d 828 (Pa. Super. 1998); *Scampono v. Highland Park Care Center, LLC*, 57 A.3d 582 (Pa. 2012). However, courts have routinely refused to extend the *Thompson* holding past such institutions to cover other entities, such as medical clinics and physician practice groups. *See Sutherland v. Monongahela Valley Hospital*, 856 A.2d 55, 62 (Pa. Super. 2004); *Dowhouer v. Judson*, 45 Pa. D. & C.4th 172, 180 (Pa.Com.Pl. 2000); *Brewer v. Geisinger Clinic, Inc.*, 45 Pa. D.

& C.4th 215, 223 (Pa.Com.Pl. 2000); *Dibble v. Penn State Geisinger Clinic, Inc.*, 42 Pa. D. & C.4th 225 (Pa.Com.Pl. 1999); *Davis v. Gish*, 5 Pa. D. & C.5th 154, 159 (Pa.Com.Pl. 2007).

There is no legal basis for holding that the purported corporate parent of a hospital can be held liable under a theory of corporate negligence. The Trustees of the University of Pennsylvania is not a hospital and cannot be held liable under a theory of corporate liability, regardless of its relationship with Pennsylvania Hospital. Moreover, as Pennsylvania Courts have consistently held, corporate negligence duties are “non-delegable,” i.e., only one entity can be held liable for a breach of these duties. The *Scamphone* Court cautioned that the trial court should ensure that “multiple entities are not exposed to liability for breach of the same non-delegable duties.” 57 A.2d at 606-07. Thus, even if a corporate negligence claim were permissible as to Pennsylvania Hospital, which is denied for the reasons stated above, The Trustees of the University of Pennsylvania, which is not a hospital, cannot also be exposed to liability for an alleged breach of the same, non-delegable duties arising out of the same factual allegations. Accordingly, even accepting as true all well pled facts in Plaintiffs’ Complaint, the corporate negligence claims as to the non-hospital Defendant, the Trustees of the University of Pennsylvania, are legally insufficient and must therefore be dismissed.

C. MOTION TO STRIKE PLAINTIFFS’ COMPLAINT FOR INSUFFICIENT SPECIFICITY AS TO THE FACTS AND ALLEGED INJURIES

Pursuant to Pa.R.C.P. 1028(a)(3), a party may file preliminary objections in the nature of a motion to strike for insufficient specificity in a pleading. A plaintiff’s Complaint is required to provide a defendant with notice of what the plaintiff’s claims are and the grounds upon which they rest, and the complaint must also formulate the issues by summarizing the facts essential to support the claims. *Alpha Tau Omega Fraternity v. The University of Pennsylvania*, 464 A.2d 1349, 1352 (Pa. Super. 1983) (*citations omitted*). Pennsylvania Rule of Civil Procedure 1019(a) provides that

“the material facts on which a cause of action or defense is based shall be stated in a concise and summary form.” Pa.R.C.P. 1019(a). As the Superior Court has noted,

Rule 1019(a) requires fact pleading. The purpose of 1019(a) is to require the pleader to disclose the material facts sufficient to enable the adverse party to prepare his case. **A complaint therefore must do more than give the defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests. It should formulate the issues by fully summarizing the material facts. Material facts are ultimate facts, i.e., those facts essential to support the claim. Evidence from which such facts may be inferred not only need not but should not be alleged. Allegations will withstand challenge under 1019(a) if (1) they contain averments of all of the facts a plaintiff will eventually have to prove in order to recover, and (2) they are sufficiently specific so as to enable defendant to prepare his defense.**

Baker v. Rangos, 324 A.2d 498, 505-506 (Pa. Super. 1974) (citations and internal quotations omitted)(emphasis added).

Further, it is well established that, with regard to the description of injuries sustained by a plaintiff, the Complaint must be stated with sufficient particularity to put the defendant on notice of evidence that may be produced at trial. *Kelly v. Martino*, 99 A.2d 901 (Pa. 1953). **A plaintiff's Complaint must set forth the extent, nature, location and duration of the injuries suffered, and injuries that are permanent should be stated specifically.** *Miller v. Perrige*, 71 Pa. D. & C.2d 476, 479–80 (Pa. Com. Pl. 1975). *See, also, Kopan v. Hawk*, 14 Pa. D. & C.2d 713, 714 (Pa. Com. Pl. 1958) (“A catchall averment of “other injuries” is nothing more than a generalized averment under which any injuries whatever could be proved at the trial. Defendant would have no knowledge in advance of the trial of what they are.”)

Plaintiffs' Complaint is woefully deficient with regard to the specificity of the allegations of the relevant facts and injuries at issue in this case. Plaintiffs' description of the material facts relating to the minor's care and treatment, diagnosis and injuries is limited to four paragraphs, which are utterly insufficient to enable defendants to prepare their defenses. *See* Exhibit “A,” ¶¶ 11-14. Plaintiffs aver that the minor was born prematurely but do not identify the gestational age

at which the child was born or his birth weight. Plaintiffs' allegation that "upon information and belief," the minor was fed Similac and/or Enfamil shortly after his birth (*Id.* at ¶ 12) does not comply with the fact-pleading requirements of Rule 1019(a), since such allegations do not provide Moving Defendants with appropriate notice of the facts as to whether the minor actually ingested cow's milk-based products. Further, plaintiffs have failed to identify which of the numerous products sold by Abbott and Mead Johnson under the Similac and Enfamil brand names were ingested by the minor. *Id.* at ¶¶ 37-38. Plaintiffs' Complaint further fails to provide a description of the material facts as to the period of time in which such products were ingested, when the minor was allegedly diagnosed with NEC and what treatment was provided for that condition.

The Complaint further fails to state the nature of the injuries and "long-term health effects" that are alleged to have resulted from the diagnosis of NEC. Plaintiffs' damages claim is not stated with particularity, is amorphous, vague, and open-ended. Pursuant to Pennsylvania pleading requirements, Moving Defendants should not be compelled to defend a claim for which the statement of injury is unspecified and subject to change.

In short, Plaintiffs' Complaint is inconsistent with the requirements of the Pennsylvania Rules of Civil Procedure as to the necessary specificity for the description of the facts and alleged injuries sustained. The facts in the Complaint are pleaded almost entirely "on information and belief." These omissions are fatal defects in Plaintiff's Complaint. Therefore, Plaintiffs' Complaint should be stricken in its entirety.

D. MOTION TO STRIKE PLAINTIFFS' CLAIMS FOR PUNITIVE DAMAGES

As in the other infant formula cases, In the *Ad Damnum* clauses of Counts VI and VII of the Complaint, Plaintiffs make baseless accusations that Moving Defendants engaged in oppressive, reckless, malicious and/or fraudulent conduct that allegedly justify an award of

punitive damages. *See* Exhibit “A,” pp. 38, 46. However, the Complaint contains no specific allegations of conduct that would permit recovery of punitive damages as to Moving Defendants. Rather, Plaintiffs merely allege that “upon information and belief” M.E. may have been given a cow’s milk-based infant formula following birth, absent any context to indicate that such an action was inappropriate based on the specific issues involved in M.E.’s medical care and condition following birth. For example, the Complaint gives no indication of whether Plaintiff-parent refused or was unable to provide breast milk and provides no information as to discussions between her and any health care providers regarding the purported use of cow’s milk-based products.

Plaintiff’s allegations of oppressive, malicious and similar conduct must be rejected as mere boilerplate. As discussed above, the FDA specifically approves the use of infant formula in care of low birth weight infants, with no restriction as to the use of cow’s milk-based products for such infants. Indeed, the fact that Plaintiffs have filed numerous lawsuits against at least four hospitals in Philadelphia based on identical claims belies the contention that Moving Defendants engaged in outrageous or malicious conduct in allegedly feeding the Plaintiff-minor with cow’s milk-based infant formula. Absent specific factual allegations to justify the claim that the use of infant formula in M.E.’s case was extreme and outrageous, there is no basis for an award of punitive damages in this case. Merely contending that punitive damages should be awarded with no supporting factual justification requires dismissal of this claim.

Since the purpose of punitive damages is not compensation of a plaintiff but punishment of the defendant and deterrence, punitive damages can be awarded only for conduct involving some element of outrage. *Hutchinson v. Luddy*, 582 Pa. 114, 870 A.2d 766 (2005). For that reason, Pennsylvania Supreme Court decisions establish that “punitive damages are an ‘extreme remedy’ available in only the most exceptional matters.” *Wagner v. Onofrey*, 2006 Pa. Dist. & Cnty. Dec.

LEXIS 333, *11 (Pa. Com. Pl. 2006) (citing *Phillips v. Cricket Lighters*, 584 Pa. 179, 188, 883 A.2d 439, 445 (2005)). “In fact, punitive damages are specifically designed to heap an additional punishment on a defendant who is found to have acted in a fashion which is particularly egregious.” *Wagner* at *12.

Punitive damages may not be awarded for misconduct that constitutes ordinary negligence such as inadvertence, mistake and errors of judgment. *Martin v. Johns-Manville Corp.*, 494 A.2d 1088, 1097 (Pa. 1985); *McDaniel v. Merck, Sharp & Dohme*, 533 A.2d 436, 437 (Pa. Super. 1987). An award of punitive damages must be supported by evidence of conduct more serious than the mere commission of the underlying tort. *Allstate Ins. Co. v. A.M. Pugh Assoc., Inc.*, 604 F. Supp. 85, 99 (M.D. Pa. 1984).

Specifically, with regard to punitive damages in the context of claims against health care providers, the Medical Care and Reduction of Error (MCARE) Act permits punitive damages only to be awarded as follows:

(a) Award. -- Punitive damages may be awarded for conduct that is the result of the health care provider’s willful or wanton conduct or reckless indifference to the rights of others. In assessing punitive damages, the trier of fact can properly consider the character of the health care provider’s act, the nature and extent of the harm to the patient that the health care provider caused or intended to cause and the wealth of the health care provider.

(b) Gross Negligence. -- A showing of gross negligence is insufficient to support an award of punitive damages.

41 P.S. §1303.505.

The Supreme Court has made clear that when assessing the propriety of the imposition of punitive damages, “the state of mind of the actor is vital. The act or failure to act, must be intentional, reckless or malicious.” *Hutchinson, supra* at 770. An appreciation of the risk is a necessary element of the mental state required for the imposition of punitive damages. *Id.* at 772.

Thus, “a punitive damages claim must be supported by evidence sufficient to establish that (1) a defendant had a subjective appreciation of the risk of harm to which the plaintiff was exposed and that (2) he acted, or failed to act, as the case may be, in conscious disregard of that risk.” *Id.*

Since professional negligence actions involve allegations that health care professionals deviated from the governing standard of care, punitive damages are generally not recoverable in malpractice actions unless the medical provider’s deviation from the applicable standard of care is so egregious as to evince a conscious or reckless disregard of a patent risk of harm to the patient. *Wagner, supra.*

Where the facts as averred show nothing more than negligence, a lapse in judgment, or mere inadvertence, courts in Pennsylvania have dismissed pleas and claims for punitive damages, often at the pleadings stage of litigation and even if the complaint alleged severe injuries or death. *See, e.g., Brownawell v. Bryan*, 40 Pa. D. & C.3d 604, 606 (Pa. Com. Pl. 1985) (dismissing punitive damages claim where a plaintiff alleged that a physician negligently performed a spinal fusion surgery that left the plaintiff with severe neurological defects, and noting that “**the mere pleading of outrageous conduct** does not, of course, satisfy the requirement stating facts which, if proven, would form a basis for a jury concluding that the conduct was such that an award of punitive damages was warranted.”) (emphasis added); *Wagner, supra* at *11 (contentions that physician failed to prescribe antibiotics, order certain tests or request an infectious disease consult constituted “nothing more than ordinary negligence and are insufficient to support an award of punitive damages.”); *McCardle v. Aldinger*, 5 Pa. D. & C.4th 421, 428 (Pa. Com. Pl. 1996) (sustaining preliminary objections and dismissing claim for punitive damages where the plaintiff alleged negligence in the prenatal care of her child that led to the child was stillborn and holding that “[i]t is not the outcome of the alleged negligence that is of consideration, but rather the alleged conduct

of defendants that is at issue.”); *Flurer v. Pocono Medical Ctr.*, 15 Pa. D. & C.4th 645, 670 (Pa. Com. Pl. 1992) (sustaining preliminary objections and finding that plaintiffs were not “capable of pleading the requisite behavior” for an award of punitive damages where a hospital allegedly failed to properly utilize a fetal monitor on a pregnant woman who was involved in a serious car accident and thereafter delivered a stillborn child).

Conversely, punitive damages have been reserved for those situations that are truly egregious and utterly outrageous, and typically involve aggravating or other factors that evince a particularly reckless mind or evil motive. *See, e.g., Medvecz v. Choi*, 569 F.2d 1221, 1227-30 (3rd Cir. 1987) (anesthesiologist who abandoned patient on operating room table and left room for a lunch break without securing a suitable replacement could be liable for punitive damages to patient who suffered irreversible paralysis from anesthesia complication that developed during his absence); *Hoffman v. Memorial Osteopathic Hospital*, 492 A.2d 1382, 386-87 (Pa. Super. 1985) (evidence that emergency room physician allowed Guillain-Barre Syndrome patient suffering from neurological paralysis to remain crying and immobile on floor for two hours as physician repeatedly stepped over patient was sufficient to support punitive damages claim); *Guernsey v. County Living Personal Care Home, Inc.*, 2006 U.S. Dist. LEXIS 31450, 2006 WL 1412765 (M.D. Pa. 2006) (punitive damages recoverable from nursing home officials who allowed resident to have access to room of 86-year old Alzheimer’s patient where he repeatedly raped her, since nursing home was aware of resident’s prior criminal convictions for sex registration as a sexual offender under Megan’s Law, and his prior instances of grabbing and kissing staff); *Lawrence v. Kunkle*, 75 D. & C. 4th 370 (Pa. Com. Pl. 2005) (patient could maintain punitive damages claim against physician who refused to perform emergency surgery because patient did not have medical

insurance even though physician knew that patient would likely suffer permanent neurologic and functional deficits if surgery was delayed).

All of the cases in the paragraph above set forth examples of egregious conduct, completely inapposite to the facts of the instant case. The facts underlying Plaintiffs' bare assertions of reckless, outrageous or similar behavior do not even remotely meet the requisite standard under Pennsylvania law that would permit an award of punitive damages. Even assuming the allegations in the Complaint were true for the purposes of this argument only, the outcome in this case was not the result of any intentional wrongdoing or deliberate misconduct on the part of Moving Defendants or any medical provider at Pennsylvania Hospital, nor does the Complaint contain any such allegations.

Additionally, pursuant to § 505(c) of the MCARE Act, punitive damages are specifically restricted in claims involving vicarious liability:

(c) Vicarious liability. -- Punitive damages shall not be awarded against a healthcare provider who is only vicariously liable for the actions of its agent that caused the injury unless it can be shown by a preponderance of the evidence that the party knew of and allowed the conduct of its agent that resulted in an award of punitive damages.

40 P.S. §1303.505(c). Plaintiffs allege in this action that unidentified "staff" fed M.E. Similac and/or Enfamil at Pennsylvania Hospital shortly after his birth and failed to warn Plaintiff-parent of the alleged risks of such products. See Exhibit "A," ¶ 12. Even if such actions were claimed to be egregious or malicious such that punitive damages were permissible, which is denied for the reasons stated above, Plaintiffs must allege facts to establish that Moving Defendants had actual knowledge of the alleged wrongful conduct and nevertheless allowed it. *See Zazzera v. Roche*, 54 D. & C. 4th 225, 238 (Pa. Com. Pl. 2001); *Dean Witter Reynolds, Inc. v. Genteel*, 499 A.2d 637 (Pa. Super. 1985). In this matter, Plaintiffs have failed to plead any facts to suggest that Moving

Defendants were aware of any alleged misconduct by any individual alleged to be an agent and allowed such conduct to continue.

For all these reasons, Plaintiffs' demand for punitive damages must be stricken with prejudice as to Moving Defendants, along with all allegations of reckless and similar conduct.

E. MOTION TO DISMISS PLAINTIFF-PARENT'S CLAIMS

1. Plaintiff-Parent has Failed to State a Cause of Action

Plaintiff-parent seeks to recover damages in her own right and as the parent and natural guardian of M.E. Plaintiffs' Complaint includes allegations in each count asserted as to Moving Defendants in which it is averred that Plaintiff-parent "suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly altered by the Injured Infant's injuries." See Exhibit "A," ¶¶ 126, 139 and 147. However, no specific cause of action is asserted as to any damages sought by Plaintiff-parent in her own right, who is not alleged in the Complaint to have suffered any physical injuries as a result of the alleged negligent conduct of Moving Defendants. For this reason, Plaintiff-parent's claim should be dismissed.

2. Plaintiffs are Required to Plead Separate Claims Pursuant to Pa.R.C.P. 1020

Further, even if Plaintiff-parent had properly articulated a cause of action in the Complaint to allow her to recover damages in her own right, the Complaint should be stricken pursuant to Pa.R.C.P. 1020(b), which provides as follows:

If persons join as plaintiffs under Rules 2228, 2229(a) or (e), the complaint shall state the cause of action, any special damage, and the demand for relief of each plaintiff in a separate count, preceded by a heading naming the parties to the causes of action therein set forth.

Accordingly, it is improper for Plaintiffs to plead in a single count claims on behalf of both the Plaintiff-minor and the Plaintiff-parent, as was done in the Complaint filed herein. Claims on

behalf of each of the Plaintiffs must be set forth in separate counts of the Complaint, specifically identifying the cause of action asserted and relief sought in each count.

3. Plaintiff-Parent's Claim Is Precluded Pursuant to the Statute of Limitations

Although the statute of limitations for claims asserted on behalf of minors are tolled until the age of majority, Plaintiff-parent's claims were not similarly tolled and were required to have been brought within two years of the alleged injury. *See Hathi v. Krewstown Park Apts*, 561 A.2d 1261 (Pa. Super. 1989); 42 Pa.C.S. § 5524. Plaintiffs allege that M.E. was born on September 28, 2007, was fed the Defendant manufacturers' products shortly after his birth, and developed NEC shortly thereafter. *See* Exhibit "A," ¶¶ 11-13. Thus, since the Complaint herein was filed on March 24, 2022, Plaintiff-parent's claims herein are clearly time-barred based on the applicable statute of limitations.


F. MOTION TO STRIKE PLAINTIFFS' COMPLAINT FOR FAILURE TO COMPLY WITH Pa.R.C.P. 1024

Pennsylvania Rule of Civil Procedure 1024(a) requires verification of every pleading containing a factual averment based upon the signer's personal knowledge or information and belief. Rule 1024(c) requires that the verification be made by one or more of the parties filing the pleading. In this case, Plaintiffs' counsel signed the verification for the Complaint, in violation of Rule 1024. *See* Exhibit "A." Accordingly, the Complaint should be stricken for lack of an appropriate verification.

V, **REQUESTED RELIEF**

For the foregoing reasons, Defendants The Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital and The Trustees of the University of Pennsylvania d/b/a Penn Medicine respectfully request that this Honorable Court sustain their Preliminary Objections and enter the attached Order.

BURNS WHITE LLC

BY: 

JAMES A. YOUNG, ESQ.


RICHARD S. MARGULIES, ESQ.

Attorneys for Defendants,

The Pennsylvania Hospital of the University of
Pennsylvania Health System d/b/a Pennsylvania
Hospital and The Trustees of the University of
Pennsylvania d/b/a Penn Medicine

CERTIFICATE OF SERVICE

I, Richard S. Margulies, Esquire, do hereby certify that on this day I caused a true and correct copy of the foregoing Preliminary Objections of Defendants The Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital and The Trustees of the University of Pennsylvania d/b/a Penn Medicine to Plaintiffs' Complaint, to be served via the electronic filing system to all counsel of record.

BY: 
RICHARD S. MARGULIES, ESQ.

Dated: June 9, 2023

EXHIBIT C

KLINE & SPECTER, P.C.

By:

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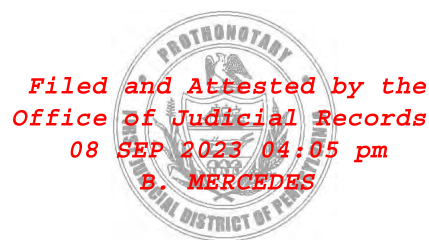
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ALICE STILLS, on her own behalf and as Parent
and Natural Guardian of M.E., a Minor,

Plaintiff,

v.

MEAD JOHNSON & COMPANY, LLC, MEAD
JOHNSON NUTRITION COMPANY, ABBOTT
LABORATORIES, THE TRUSTEES OF THE
UNIVERSITY OF PENNSYLVANIA d/b/a PENN
MEDICINE, and PENNSYLVANIA HOSPITAL OF THE
UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM
d/b/a PENNSYLVANIA HOSPITAL,

Defendants.

: **IN THE COURT OF COMMON PLEAS**
: **PHILADELPHIA COUNTY**
:
: **CIVIL TRIAL DIVISION**
:
: **MARCH TERM 2022**
: **NO. 2617**

NOTICE TO PLEAD AND DEFEND

NOTICE

You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so the case may proceed without you and a judgment may be entered against you by the court without further notice for any money claimed in the complaint or for any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER

ADVISO

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ALICE STILLS, on her own behalf and as Parent
and Natural Guardian of M.E., a Minor,

Plaintiff,

v.

MEAD JOHNSON & COMPANY, LLC, MEAD
JOHNSON NUTRITION COMPANY, ABBOTT
LABORATORIES, THE TRUSTEES OF THE
UNIVERSITY OF PENNSYLVANIA d/b/a PENN
MEDICINE, and PENNSYLVANIA HOSPITAL OF THE
UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM
d/b/a PENNSYLVANIA HOSPITAL,

Defendants.

: **IN THE COURT OF COMMON PLEAS**
: **PHILADELPHIA COUNTY**
:
: **CIVIL TRIAL DIVISION**
:
: **MARCH TERM 2022**
: **NO. 2617**

FIRST AMENDED COMPLAINT

Plaintiff brings this Amended Complaint and Demand for Jury Trial (the “Amended Complaint”) against Mead Johnson & Company, LLC, Mead Johnson Nutrition Company, and Abbott Laboratories (collectively “the Defendant Manufacturers”), and The Trustees of the University of Pennsylvania d/b/a Penn Medicine and Pennsylvania Hospital of the University of

Pennsylvania Health System d/b/a Pennsylvania Hospital (collectively “Penn Medicine” or “Pennsylvania Hospital”), together “Defendants.” Plaintiff alleges the following upon personal knowledge as to Plaintiff’s own acts and experiences and upon information and belief, including investigation conducted by Plaintiff’s attorneys, as to all other matters.

I. INTRODUCTION

1. This action arises out of the injuries suffered by a premature infant (the “Injured Infant”) who was given the Defendant Manufacturers’ cow’s milk-based infant feeding products at Pennsylvania Hospital. Pennsylvania Hospital, managed by Penn Medicine, acquired and supplied the Defendant Manufacturers’ products to the Injured Infant and negligently failed to warn of their unreasonably dangerous properties in a reasonable manner. This caused the Injured Infant to develop necrotizing enterocolitis (“NEC”), a life-altering and potentially deadly disease that largely affects premature babies who are given cow’s milk-based feeding products. As a result, the Injured Infant was seriously injured, resulting in long term health effects and accompanying harm to their parent (“the Plaintiff Parent”).

2. Plaintiff brings these causes of action against Defendants to recover for injuries that are the direct and proximate result of the Injured Infant’s consumption of the Defendant Manufacturers’ unreasonably dangerous cow’s milk-based infant feeding products, which were acquired and supplied without adequate warning to the Injured Infant at Pennsylvania Hospital, owned and operated by Penn Medicine.

II. PARTIES

3. Plaintiff Alice Stills is a natural adult person and a resident of Pennsylvania. Ms. Stills is the parent and natural guardian of M.E., a minor. Ms. Stills’s address is 656 N Conestoga Street, Philadelphia, Pennsylvania 19131.

4. Defendant Mead Johnson Nutrition Company is a corporation, incorporated under the laws of the State of Delaware. Its principal place of business is Illinois. Defendant Mead Johnson & Company, LLC, is a limited liability company, organized under the laws of the State of Delaware. Its citizenship is that of its sole member, Mead Johnson Nutrition Company. Defendants Mead Johnson Nutrition Company and Mead Johnson & Company, LLC, (together, “Mead”) are manufacturers of cow’s milk-based infant feeding products and market many of these products under the “Enfamil” brand name.

5. Defendant Abbott Laboratories (“Abbott”) is a corporation, incorporated under the laws of the State of Illinois. Its principal place of business is in Illinois. Abbott is a manufacturer of cow’s milk-based infant feeding products and markets many of its products under the “Similac” brand name.

6. Defendant The Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital is a non-profit corporation incorporated and registered to do business under the laws of the Commonwealth of Pennsylvania. Its principal place of business is Philadelphia, Pennsylvania. Pennsylvania Hospital is a registered name of The Pennsylvania Hospital of the University of Pennsylvania Health System. The sole member of The Pennsylvania Hospital of the University of Pennsylvania Health System is The Trustees of the University of Pennsylvania.

7. Defendant The Trustees of the University of Pennsylvania d/b/a Penn Medicine is a non-profit corporation registered to do business in the Commonwealth of Pennsylvania. Its principal place of business is Philadelphia, Pennsylvania. Penn Medicine is a registered name of The Trustees of the University of Pennsylvania.

III. JURISDICTION AND VENUE

8. This Court has jurisdiction in this matter pursuant to 42 Pa. C.S.A. § 931. Defendants conduct authorized business in the Commonwealth of Pennsylvania. They have sufficient minimum contacts with and purposefully avail themselves of the markets of this Commonwealth. This suit arises out of Defendants' forum-related activities, such that the Court of Common Pleas of Philadelphia County's exercise of jurisdiction would be consistent with traditional notions of fair play and substantial justice.

9. Venue is proper in the Court of Common Pleas of Philadelphia County pursuant to Rules 1006(b), 1006(c)(1), and 2179(a) of the Pennsylvania Rules of Civil Procedure because Defendants are corporations or similar entities that regularly conduct business in Philadelphia County, which is also the county where Plaintiff's causes of action arose, and the county where the occurrences took place out of which Plaintiff's causes of action arose.

10. This action is not subject to the Compulsory Arbitration Program of the Court of Common Pleas of Philadelphia County because the amount in controversy, excluding interest and costs, is in excess of \$50,000.

IV. FACTUAL ALLEGATIONS

M.E.'s NEC Diagnosis

11. M.E. was born prematurely at Pennsylvania Hospital in Philadelphia, Pennsylvania on September 28, 2007.

12. At birth, M.E.'s gestational age was approximately 28 weeks and he weighed 907 grams. Upon information and belief, M.E. was fed Similac and/or Enfamil cow's milk-based products by staff at Pennsylvania Hospital after his birth.

13. Upon information and belief, M.E. developed NEC after ingesting Defendant Manufacturers' products.

14. M.E.'s diagnosis of NEC occurred during his course of treatment at Defendant Hospital's NICU. M.E. suffered injuries, including but not limited to, a diagnosis of NEC, treatment with antibiotics and surgery, feeding difficulties, neurological injuries, developmental delays, and growth issues and he continues to suffer other long-term health effects.

***Cow's Milk-Based Feeding Products Are Known to Cause
NEC***

15. NEC is a devastating disease that is the most frequent and lethal gastrointestinal disorder affecting preterm infants. NEC develops when harmful bacteria breach the walls of the intestine, causing portions of the intestine to become inflamed and often to die. Once NEC develops, the condition can progress rapidly from mild feeding intolerance to systemic and fatal sepsis. Up to 30 percent of NEC-diagnosed infants die from the disease.

16. Preterm and low-birth-weight infants are especially susceptible to NEC because of their underdeveloped digestive systems. Extensive scientific research, including numerous randomized controlled trials, has confirmed that cow's milk-based feeding products cause NEC in preterm and low-birth-weight infants, which in turn may lead to other medical complications, surgeries, long-term health problems, and death.

Safer, Nutritionally Superior Alternatives to Cow's Milk-Based Products Exist

17. A range of options are available that allow preterm and low-birth-weight infants to be fed exclusively human milk-based nutrition. For example, in addition to the mother's own milk, an established network delivers pasteurized donor breast milk to hospitals nationwide. Moreover, hospitals have access to shelf-stable formula and fortifiers derived from pasteurized breast milk.

18. A diet based exclusively on breast milk and breast milk fortifiers provides all the nutrition necessary to support premature and low-birth-weight infants without the elevated risk of NEC associated with cow's milk-based products.

19. The Defendant Manufacturers' products not only pose a threat to infants' health, but also displace the breast milk they could otherwise receive. This displacement only increases infants' vulnerability to NEC.

20. Breast milk-based nutrition nourishes infants while creating a significantly lower risk of NEC.

21. At the time the Injured Infant was fed the Defendant Manufacturers' products, the science clearly demonstrated to Defendants that these products cause NEC and greatly increase the likelihood that a baby will develop NEC, leading to severe injury and often death.

22. Despite the scientific consensus that the Defendant Manufacturers' cow's milk-based products present a dire threat to the health and development of preterm infants, the Defendant Manufacturers have made no changes to their products or the products' packaging, guidelines, instructions, or warnings. Instead, they have continued to sell their unreasonably dangerous products. In addition, they incentivize hospitals that know the risks to use their products by providing them to the hospital for free or at a significant discount, in order that vulnerable infants and their families will become accustomed to using their products before discharge. And, in fact, the Defendant Manufacturers offer contracts to hospitals—which the hospitals accept—that actually *prevent* the health care providers from offering alternative products—even safer ones—on pain of risking the hospital's advantageous formula pricing strategy.

Ms. Stills Discovers Her Claim

23. Because of the Defendants' concealment and misrepresentations, described more fully herein, Ms. Stills did not know, and had no reason to know or suspect, that M.E.'s NEC could have been caused by the Defendant Manufacturers' products.

***Despite Exercising Diligence, a Reasonable Investigation Did Not Reveal and
Would Not Have Revealed a Factual Basis Earlier
Because Defendants Hid the Cause of NEC from Ms. Stills***

24. Despite exercising reasonable diligence, Ms. Stills was unable to have made the discovery earlier via a reasonable investigation because the Defendants in this litigation concealed the wrongful cause of M.E.'s injuries.

25. Not one person at Penn Medicine mentioned that the Defendant Manufacturers' formula products could have caused M.E.'s injuries. Penn Medicine's response at the time did not give Ms. Stills any reason to suspect any wrongdoing on the part of the Defendants.

26. Ms. Stills is a layperson with no medical background or training that would have given her any reason to doubt the response she received from her Penn Medicine health care providers at the time.

27. Given that Penn Medicine's health care providers were in charge of the care of her newborn infant, Ms. Stills had no reason to doubt their word.

28. Additionally, the risk of necrotizing enterocolitis was not disclosed on the labeling or packaging of *any* of the Defendant Manufacturers' products.

29. What is more, necrotizing enterocolitis is a disease that can occur in children who are *not* fed the Defendant Manufacturers' products, and the Defendant Manufacturers have worked to mislead parents into a false sense of security about the use of those products. Publicly disseminated materials from each Defendant Manufacturer disguise the role their products play in causing the disease—and affirmatively say, even today, that their products are safe and do not cause NEC. In fact, some publicly disseminated materials from the formula manufacturers even suggest that formula may help *reduce* the risk of this terrible and potentially fatal disease.

30. For example, Abbott’s website stays that “[t]he specific cause of NEC is unknown, but it’s most often seen in very low birth weight premature babies,” and that “about 10% of babies who are born prematurely develop NEC.” The website suggests that “new preliminary studies” suggest for the first time that “NEC prevention may . . . be possible” with the use of human milk oligosaccharides to “dramatically curb intestinal inflammation” and reduce the risk of NEC. Abbott states that these human milk oligosaccharides are found in “certain Similac formulas” although they are “not currently available in Similac’s premature infant formulas.”¹ Likewise, the website for Mead Johnson’s products states that necrotizing enterocolitis is “one of the most common and serious intestinal disease[s] among premature babies.” And it deflects responsibility from Mead Johnson’s products: “Necrotizing enterocolitis happens when tissue in the small or large intestine is injured or inflamed.”²

31. Because of the misleading information distributed by the Defendant Manufacturers, as further detailed below, a reasonable person would not suspect that the Defendant Manufacturers’ products could have caused M.E.’s injuries.

32. Ms. Stills also did not know, and had no reason to know or suspect, that Penn Medicine breached its duty of care by distributing the Defendant Manufacturers’ products to him. Not only was Ms. Stills unaware that the Defendant Manufacturers’ products caused M.E.’s injuries, but the Defendant Manufacturers’ distribution agreements with Penn Medicine—which allowed Penn Medicine to secure sweetheart deals for otherwise expensive premature infant formula in exchange for product placement and access to the hospital staff—were also not public or knowable to Ms.

¹ The Role of HMOs in Reducing NEC, <https://www.nutritionnews.abbott/pregnancy-childhood/prenatal-breastfeeding/the-promising-role-of-hmos-in-reducing-risk-of-nec/> (last visited July 28, 2023).

² Special Feeding Concerns for Preemies, <https://www.enfamil.com/articles/special-feeding-concerns-for-preemies/> (last visited July 29, 2023).

Stills, nor could any reasonable investigation outside of litigation have uncovered the terms of those agreements.

Despite Exercising Reasonable Diligence, the Defendants' Fraudulently Concealed the Risks of NEC from Defendant Manufacturers' Products to Divert, Prevent, and Mislead Plaintiff Regarding the Cause of Her Child's NEC Diagnosis

33. In addition to the averments above, the Defendants have acted in concert to fraudulently convey false and misleading information concerning the risk of NEC, and potentially death, caused by Defendant Manufacturers' preterm infant formula products.

34. The Defendants' actions as set forth herein constitute knowing misrepresentation, omission, suppression, and concealment of material facts, made with the intent that Plaintiff would rely upon such concealment, suppression, or omission, in connection with the use of Defendants' preterm infant products.

35. Plaintiff did not know, and could not learn, the truth concerning the uses, risks and benefits of Defendant Manufacturers' preterm infant products due to Defendants' deliberate misrepresentations and concealment, suppression and omission of material facts and important information regarding the risks of NEC, and potentially death, from the products.

36. Moreover, Defendant Hospital further participated in the intentional concealment—on information and belief, it allowed the Defendant Manufacturers' sales representatives into its hospital to provide samples and free products that did not warn of their serious dangers, and to provide “education” to its NICU staff that was incomplete as to the true risks of feeding their patients the Defendant Manufacturers' products.

37. Additionally, Defendant Hospital failed to inform Ms. Stills that the Defendant Manufacturers' products caused Plaintiff's NEC. As noted above, after learning of Plaintiff's NEC diagnosis, Ms. Stills was understandably concerned about the degrading health of her newborn

infant. But even though Defendant Hospital knew of the increased risk of NEC from formula, it did not disclose that the formula provided to M.E. could increase the risk of NEC to preterm infants. Not one person at the NICU mentioned that the Defendant Manufacturers' formula products could have been the cause of Plaintiff's injuries.

38. Defendant Hospital was aware that the Defendant Manufacturers' products caused NEC in premature infants. Defendant Hospital was also aware that the Defendant Manufacturers did not provide warnings on their products. However, Defendant Hospital did not warn Ms. Taylor of the risks of the products. Instead, and notwithstanding the sweetheart deal Defendant Hospital agreed to in exchange for preterm infant formula at little to no cost, Defendant Hospital repeatedly informed Ms. Stills that it would do everything it could possibly do to keep her infant safe. Though this was clearly not true given the known risks of preterm formula for babies like M.E., it was enough for Ms. Stills to trust that Defendant Hospital was providing preterm formula in the best interest of her child.

39. Defendants' affirmative acts of fraud and concealment, as averred herein, diverted, prevented, and/or mislead Plaintiff from discovering the medical cause of her child's NEC diagnosis.

The Defendant Manufacturers' False and Misleading Marketing Regarding Cow's Milk-Based Infant Products

40. Abbott and Mead have aggressively marketed their cow's milk-based products as medically endorsed and nutritionally equivalent alternatives to breast milk, including prior to the Injured Infant's birth.

41. Abbott's and Mead's marketing approach includes targeting the parents of preterm infants while they are still in the hospital with messages that the Defendant Manufacturers' cow's milk formulas and fortifiers are necessary for the growth and development of their vulnerable children.

Often these tactics implicitly discourage mothers from breastfeeding, which reduces the mother's supply of breast milk. None of the Defendant Manufacturers' marketing materials, including their promotional websites, reference the science showing how significantly their products increase the risk of NEC.

42. Undoubtedly aware of the impact of their advertising, the Defendant Manufacturers, along with other formula manufacturers, are willing to spend massive sums to disseminate their message.

43. Recognizing the abuse and dangers of infant formula marketing, in 1981, the World Health Assembly—the decision-making body of the World Health Organization—developed the International Code of Marketing of Breast-milk Substitutes (“the Code”), which required companies to acknowledge the superiority of breast milk, the negative effect on breastfeeding of introducing partial bottle-feeding, and the difficulty of reversing the decision not to breastfeed. The Code also forbade advertising or other forms of promotion of formula to the general public, as well as providing sample products to mothers or members of their families.

44. While Abbott and Mead acknowledge the Code on their websites and claim to support the effort to encourage mothers to breastfeed for as long as possible, this is little more than lip service. Instead, the Defendant Manufacturers' aggressive marketing exploits new parents' darkest fears—that the nutrition they are supplying to their child will not provide the best chance of survival—while wholly failing to warn that their products come with a significantly increased risk of NEC.

45. For example, Abbott's website, on a page titled “Infant Formula Marketing,” states: “We agree with the World Health Organization that breastfeeding provides the best nutrition for babies, and we support its goal to increase breastfeeding. We also recognize that for infants who aren't breastfed—for medical reasons or otherwise—infant formula is the only appropriate, safe

alternative to meet babies' nutritional needs." This statement ignores the existence of donor milk, as well as human milk-based formula.

46. Abbott markets and sells multiple products specifically targeting preterm and low-birthweight infants, including Liquid Protein Fortifier, Similac NeoSure, Similac Human Milk Fortifiers, Similac Special Care 20, Similac Special Care 24, Similac Special Care 24 High Protein, and Similac Special Care 30. In advertising these products, Abbott emphasizes the products' purported ability to assist underdeveloped babies in reaching their growth targets. For example, on the since-edited webpage regarding Similac NeoSure, Abbott noted: "Your premature baby didn't get her full 9 months in the womb, so her body is working hard to catch up. During her first full year, feed her Similac NeoSure, a nutrient-enriched formula for babies who were born prematurely, and help support her development." Yet, no mention was made of the accompanying significantly increased risk of NEC. At some point, the website was edited to remove this statement. However, upon information and belief, the statement remained on the website until at least December 2020.

47. Mead markets and sells multiple products specifically targeting premature infants, including Enfamil NeuroPro EnfaCare Infant Formula, Enfamil Premature Infant Formula 24 Cal High Protein, Enfamil Premature Infant Formula 30 Cal with Iron, Enfamil Premature Infant Formula 24 Cal with Iron, Enfamil Premature Infant Formula 20 Cal with Iron, Enfamil 24 Cal Infant Formula, and Enfamil Human Milk Fortifier (acidified liquid and powder). In advertising these products, Mead emphasizes the purported similarities between its formula and breast milk, while failing to include any information about the nutritional deficits and dangers that accompany formula use. For example, the since-edited webpage for Enfamil Enfacare stated: "Premature babies fed Enfamil® formulas during the first year have achieved catch-up growth similar to that

of full term, breastfed infants” and noted that Enfamil formulas include “expert-recommended levels of DHA and ARA (important fatty acids found naturally in breast milk) to support brain and eye development.”

48. One Enfamil advertisement, introducing a new product line called Enfamil NeuroPro, is entirely focused on favorably comparing Enfamil’s formula to breast milk, without any mention of the product’s extreme risks. Indeed, the terms “human milk” and “breast milk” are used 13 times in the advertisement, including in such statements as “for decades human milk has inspired the advancements in Enfamil formulas and now through extensive global research, we are taking an even closer look at human milk” and “only Enfamil NeuroPro has a fat blend of MFGM and DHA previously found only in breast milk.” The webpage for the product has made similar manipulative claims, stating “Enfamil is backed by decades of breast milk research and multiple clinical studies” and it claims that “to create our best formulas, we collaborated on some of the most extensive breast milk studies to date[.]”

49. Formula manufacturers have long used their relationships with hospitals and the discharge process to encourage parents to substitute formula for breast milk. They offer free or reduced-cost formula to hospitals for use with infants before discharge. And they offer free formula, coupons, and even entire gift baskets to parents before their infants’ discharge from the NICU or hospital.

50. Through this early targeting, the Defendant Manufacturers create brand loyalty under the guise of a “medical blessing,” in hopes that new parents continue to use formula after they leave the hospital, resulting in increased expense for parents, significantly increased risk for babies, and increased profit for the Defendant Manufacturers. The Defendant Manufacturers’ giveaways and gift baskets send confusing signals to mothers who are simultaneously being encouraged to breastfeed by their healthcare professionals, and they have been shown to negatively impact

breastfeeding rates.

51. Further, when the Defendant Manufacturers recognized a shift in the medical community towards an exclusive breast milk-based diet for premature infants, Abbott developed a product called “Similac Human Milk Fortifier,” and Mead developed “Enfamil Human Milk Fortifier.” These names are misleading in that they suggest that the products are derived from breast milk, when, in fact, they are cow’s milk-based products. The packaging appears as:



52. The Defendant Manufacturers have designed powerful misleading marketing campaigns to deceive parents into believing that: (1) cow’s milk-based products are safe, including for preterm infants; (2) cow’s milk-based products are equal, or even superior, substitutes to breast milk; (3) cow’s milk-based products are necessary for proper growth and development of preterm infants; and (4) physicians consider the Defendant Manufacturers’ cow’s milk-based products to be a first

choice. This marketing scheme is employed despite all Defendants knowing of and failing to warn of the extreme risk of NEC and death that cow's milk-based products pose to preterm infants like the Injured Infant.

53. The Defendant Manufacturers have also designed powerful marketing campaigns to both the general public and health care providers at hospitals like Pennsylvania Hospital. The Defendant Manufacturers know that sales made to hospitals are key drivers of brand loyalty, and thus are a key opportunity to drive better downstream business—*i.e.*, retail purchases by parents after they have left the hospital. On information and belief, the Defendant Manufacturers know that the formula products used in a hospital's NICU are related to getting and keeping the overall hospital contracts. And the Defendant Manufacturers know that, just like any celebrity endorsement, when mothers of newborn infants see medical professionals using a certain brand, the mothers are more likely to continue to purchase that same brand after discharge. The Defendant Manufacturers are thus heavily motivated to ensure that NICU departments are using their products.

54. Abbott and Mead Johnson focus their sales teams and training heavily on hospital NICU departments. They train their sales representatives how to increase the number of babies on their formula, and they emphasize the need to be the dominant formula manufacturer in the NICU so they can own that profitable ground and secure a great return on their substantial investment in NICU formula and other products.

55. To leverage hospitals' NICUs and secure babies in the hospital and at retail, the Manufacturer Defendants pull out all the stops to convince hospitals, including Defendant Hospital, to purchase their products. For example: Abbott and Mead Johnson provide samples of their products to hospitals for free.

56. On information and belief, to get the hospitals on board with supplying their formula for premature infants, Abbott and Mead Johnson work with hospitals to secure contracts that have special pricing discounts if a certain level of the formula-fed babies in the hospital receive just that one manufacturer's products; similar to a restaurant being a Coke or Pepsi restaurant. And notwithstanding the increased risk of the Defendant Manufacturers' products for the hospitals' most fragile patients—the preterm infants—the decision makers at these hospitals seek out these types of contracts to better the hospitals' own bottom lines.

57. On information and belief, Abbott and Mead Johnson also seek promises and/or assurances that the full range of health care providers at the hospitals, including the nurse practitioners and other staff who would pull the infant formula off the shelf, are grabbing the respective company's own formula products to give to the preterm infants. The goal of this tactic was to ensure that the Defendant Manufacturers and key people at the hospital would be sending a shared message that the preterm infant formula products were safe and without risk, even though that is not what the science said.

58. Prior to M.E.'s birth, Abbott sent sales representatives to Defendant Hospital. Those sales representatives provided information about Abbott's products to Defendant Hospital's staff via conversations, presentations, and written pamphlets. This information indicated that Abbott's products were safe to give to preterm infants like M.E. Abbott maintains call logs that detail which sales representatives visited the hospitals, which days they visited, and which products they discussed. These sales representatives did not disclose that Abbott's products could cause NEC in preterm infants.

59. Prior to M.E.'s birth, Mead Johnson sent sales representatives to Defendant Hospital. Those sales representatives provided information about Mead Johnson's products to Defendant

Hospital's staff via conversations, presentations, and written pamphlets. This information indicated that Mead Johnson's products were safe to give to preterm infants like M.E. Mead Johnson maintains call logs that detail which sales representatives visited the hospitals, which days they visited, and which products they discussed. These sales representatives did not disclose that Mead Johnson's products could cause NEC in preterm infants.

60. Mead Johnson and Abbott believed and intended that the misrepresentations that its sales representatives shared with Defendant Hospital would be used to make feeding decisions for preterm infants like M.E.

The Defendant Manufacturers' Inadequate Warnings

61. Although Mead promotes an aggressive marketing campaign designed to convince parents that its cow's milk-based products are safe and necessary for the growth of a premature infant, the product is in fact extremely dangerous for premature infants. Enfamil products significantly increase the chances of a premature infant developing potentially fatal NEC.

62. The Enfamil products Mead markets specifically for premature infants are commercially available at retail locations and online. No prescription is necessary.

63. Despite knowing of the risk of NEC, the packaging of Mead's products does not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with Mead's products, or of the magnitude of this increased risk. Mead likewise did not provide instructions or guidance for how to avoid NEC.

64. Mead cites no medical literature or research to guide the use of its products.

65. Despite knowing of the risk of NEC, Mead did not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with its products, or of the magnitude of this increased risk. Mead likewise did not provide instructions or guidance for how to avoid NEC.

66. Mead deceived the public, parents, physicians, other medical professionals, and medical staff into believing that Enfamil products were a safe and necessary alternative, supplement and/or substitute to breast milk.

67. Mead Johnson failed to provide, and continues to fail to provide, a full accounting of the risk of NEC as documented, by underrepresenting and misrepresenting the risk to the public and the medical community.

68. Despite knowing that its products were being fed to premature infants, often without the parents' informed consent, Mead failed to require or recommend that medical professionals inform parents of the significant risk of NEC or to require that parental consent be obtained prior to the products being fed to their babies. Like Mead, Abbott promotes an aggressive marketing campaign designed to make parents believe that its products are safe and necessary for the growth of premature infants, despite the products in fact being extremely dangerous for premature infants. Abbott's products significantly increase the chances of a premature infant getting potentially fatal NEC.

69. The products Abbott markets specifically for premature infants are available at retail locations and online. No prescription is necessary.

70. Despite knowing of the risk of NEC, Abbott did not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with its products, or of the magnitude of this increased risk. Abbott likewise did not provide instructions or guidance for how to avoid NEC.

71. Abbott deceived the public, parents, physicians, other medical professionals, and medical staff into believing that its products were a safe and necessary alternative, supplement and/or substitute to breast milk.

72. Despite knowing of studies documenting an increased risk of NEC from its products, Abbott did not act to make parents or the medical community aware of those risks, and instead took steps to conceal or prevent those risks from becoming public. Despite knowing that its products were being fed to premature infants, often without the parents' informed consent, Abbott failed to require or recommend that medical professionals inform parents of the significant risk of NEC or to require that parental consent be obtained prior to the products being fed to their babies.

Penn Medicine's Failure to Warn

73. On information and belief, Penn Medicine, which operates Pennsylvania Hospital, was aware of the significantly increased risk of NEC and death associated with providing Abbott's and Mead's cow's milk-based products to its premature infant patients. It knew or should have known that feeding these cow's milk-based products can cause NEC in premature infants who otherwise would not have developed this devastating condition. However, instead of warning of the dangers, or supplying breast milk-based feeding products to preterm infants like the Injured Infant, Penn Medicine has continued to source, distribute, and supply the Defendant Manufacturers' products in its hospitals without any adequate warning.

74. To that end, Penn Medicine has participated in studies designed to increase the use of donor milk while, at the same time, reducing formula feeding in neonates. The University of Pennsylvania School of Nursing, an affiliate of Penn Medicine, has conducted extensive research into the risks associated with feeding formula to premature infants. It recently partnered with the National Institute of Nursing Research to publish clinical determinations based on its experience "changing hospital systems and influencing policy," and its findings were unequivocal:

This is what we know about the science of human milk: it reduces the risk of necrotizing enterocolitis, reduces the risk of infection, [and] creates greater enteral feed tolerance and more rapid weaning from intravenous nutrition. . . .

Other Penn Medicine research has similarly concluded that "[h]uman milk decreases the incidence

and severity of . . . necrotizing enterocolitis (NEC).”

75. Penn Medicine also purports to adhere to the tenets of the “Baby Friendly Hospital Initiative,” which seeks to increase rates of breastfeeding initiation, exclusivity, and diet duration. The “Baby Friendly Hospital Initiative” specifically targets a reduction in the rates of NEC in preterm infants by encouraging implementation of exclusive breast milk diets among new mothers. Although Pennsylvania Hospital has maintained its “Baby Friendly” designation for years, it has not eliminated or restricted the use of formula or fortifier for preterm infants in its hospitals.

76. Finally, medical providers and staff at Penn Medicine have acknowledged the risks associated with providing the Defendant Manufacturers’ cow’s milk-based products to premature infant patients instead of breast milk-based nutrition. In an internal newsletter from 2012 touting donor milk programs, Penn Medicine acknowledged the benefits of a human milk-based diet, quoting a staff lactation consultant:

Donor milk is not inexpensive. It costs about \$4.25 per ounce, but the return on investment is huge. “Preemies given mother’s milk get discharged three to four days sooner and also have a six to 10 times lower risk of getting a gastrointestinal complication called necrotizing enterocolitis,” Carpenter said, adding that the infection can cost up to \$250,000 to treat. The average cost to provide a preemie with donor milk: \$125.

77. These statements demonstrate that Penn Medicine knew or should have known of the high increased risk of NEC for premature infants posed by the Defendant Manufacturers’ products.

78. Although Penn Medicine knew or should have known of the serious danger of the Defendant Manufacturers’ products, it has continued to purchase, supply, and distribute these products to preterm infants without providing full and adequate warnings of the attendant risks to parents, healthcare professionals, and other medical staff at its relevant facilities. As a result, the Injured Infant was fed the Defendant Manufacturers’ cow’s milk-based products at Pennsylvania

Hospital, causing their injuries. This occurred even though hospitals across the country, including Pennsylvania Hospital, warn and obtain consent from parents before providing other safer forms of nutrition, such as donor breast milk.

79. Penn Medicine's failure to warn of the risks posed by the Defendant Manufacturers' products is entrenched (and compounded) by the financial benefits it accrues from its relationships with the Defendant Manufacturers. On information and belief, it has received the Defendant Manufacturers' cow's milk-based products for free and/or at a significant discount, and has granted their sales representatives access to its healthcare professionals and medical staff. These sales representatives have provided deceptive information that Penn Medicine reasonably knew or should have known would ultimately reach parents through those staff. This arrangement dovetails with the Defendant Manufacturers' own marketing strategies" and use of salespersons.

Safer Alternative Designs

80. The Defendant Manufacturers' cow's milk-based products made specifically for premature infants are unreasonably unsafe for those infants. The Defendant Manufacturers could have used pasteurized breast milk instead of cow's milk in their products, which would have produced a safer product.

81. Prolacta Bioscience manufactures and sells breast milk-based feeding products, specifically designed for preterm infants, which contain no cow's milk. This alternative design provides all the necessary nutrition for growth and development that cow's milk-based products provide, without the same unreasonably dangerous and deadly effects.

82. On information and belief, Abbott and Mead were aware of the significantly increased risk of NEC and death associated with their cow's milk-based products, and instead of warning of the dangers, or removing them altogether, Abbott and Mead have continued to use cow's milk as the

foundation of their products.

CAUSES OF ACTION
COUNT I: STRICT LIABILITY FOR DESIGN DEFECT
(Against Abbott and Mead)

83. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

84. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to manufacture, sell, and distribute their products in a manner that was not unreasonably dangerous.

85. Abbott and Mead also owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to manufacture, sell, and distribute their products in a manner that was merchantable and reasonably suited for their intended use.

86. Abbott and Mead knew that their products would be used to feed premature infants like the Injured Infant and knew (or reasonably should have known) that use of their cow's milk-based products significantly increased the risk of NEC, serious injury, and death, and that such use was therefore unreasonably dangerous to premature infants, not reasonably suited for the use intended, not merchantable, and had risks that exceeded a reasonable buyer's expectations. Nonetheless, they continued to sell and market their defective products as appropriate for premature infants.

87. The Injured Infant ingested Abbott and/or Mead's unreasonably dangerous cow's milk-based products. The risks of feeding those products to the Injured Infant outweighed the benefits. An ordinary consumer would not expect those products to carry a significant risk of serious injury and death from NEC.

88. Abbott and Mead knew (or reasonably should have known) that breast milk-based nutrition did not carry the same risks of NEC, serious injury, and death that their products do.

89. Abbott's and Mead's products contained cow's milk at the time they left the manufacturing facility.

90. Abbott and Mead did not develop a human-milk based product that was safer for premature infants and did not reformulate their products to reduce the risk of NEC, serious injury, and death, even though doing so was economically and technologically feasible and even though pasteurized breast milk was an available alternative.

91. Abbott's and/or Mead's products were fed to the Injured Infant, which caused and/or increased the risk of their NEC and injuries.

92. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;

- d. For punitive damages in excess of \$50,000 and this Court's arbitral limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT II: STRICT LIABILITY FOR FAILURE TO WARN
(Against Abbott and Mead)**

93. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

94. Abbott and Mead, as the manufacturers and/or sellers of the infant products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide adequate warnings or instructions about the dangers and risks associated with the use of their products with preterm infants, specifically including but not limited to the risk of NEC, serious injury, and death.

95. Abbott's and Mead's duty to warn is part of their general duty to design, manufacture, and sell their infant products in a manner that is reasonably safe for their foreseeable uses. By designing their products with cow's milk-based ingredients, Abbott and Mead undertook a duty to warn of the unreasonable risk of harm posed by those ingredients, specifically including the significantly increased risk of NEC, severe injury, and death. The failure to warn makes the products at issue in this litigation unreasonably dangerous.

96. Specifically, Abbott and Mead breached their duty to warn of the foreseeable risks of the infant products at issue in this litigation because they knew or should have known that their

cow's milk-based premature infant products would be fed to premature infants like the Injured Infant, and that their products might cause the Injured Infant to develop NEC, severe injury, or death, yet they failed to provide adequate warnings of those risks. Among other risks, the Defendant Manufacturers:

- a. Failed to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death for the Injured Infant; and/or
- b. Failed to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or
- c. Inserted warnings and instructions on their products that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC and death; and/or
- d. "Black box"-type warning that their cow's milk-based products are known to significantly increase the risk of NEC and death when compared to breast milk in premature infant; and/or
- e. Failed to disclose well-researched and well-established studies that linked cow's milk-based products to NEC and death in premature infants; and/or
- f. Failed to insert a warning or instruction to healthcare professionals and other medical staff in the hospital that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risks; and/or
- g. Failed to provide a warning in a method reasonably calculated or expected

to reach the parents of newborns, like the Plaintiff Parent; and/or

- h. Failed to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products.

97. Abbott's and Mead's products contained cow's milk at the time they left the manufacturing facility.

98. As a direct and proximate result of the inadequacy of the warnings and the pervasive marketing campaigns suggesting the safety and necessity of the Defendant Manufacturers' products, the Injured Infant were fed cow's milk-based products, which caused and/or increased risk of their developing NEC.

99. The unwarned-of risks are not of a kind that an ordinary consumer would expect. Had physicians and medical staff known of the extreme risk associated with feeding premature infants cow's milk-based formula, they would not have fed the Injured Infant those products. Had the Plaintiff Parent known of the significant risks of feeding the Injured Infant cow's milk-based formula, they would not have allowed such products to be fed to the Injured Infant.

100. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of

enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;

- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitral limit resulting from the Defendants Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT III: NEGLIGENCE
(Against Abbott and Mead)**

101. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

102. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to exercise reasonable care to design, test, manufacture, inspect, and distribute a product free of unreasonable risk of harm to users, when such products are used in their intended manner and for their intended purpose.

103. At all times relevant to this action, the Injured Infant's healthcare professionals and medical

staff used the products at issue in their intended manner and for their intended purpose.

104. Abbott and Mead, directly or indirectly, negligently, and/or defectively made, created, manufactured, designed, assembled, tested, marketed, sold, and/or distributed the cow's milk-based infant products at issue in this litigation and thereby breached their duty to the general public and the Plaintiff Parent.

105. Specifically, although Abbott and Mead knew or reasonably should have known at the time of production that their cow's milk-based infant products significantly increased the risk of NEC, serious injury, and death, they failed to act in a reasonably prudent manner and breached their duty by:

- a. Failing to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death for the Injured Infant; and/or
- b. Failing to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or
- c. Inserting warnings and instructions that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC and death; and/or
- d. Failing to insert a large and prominent "black box"-type warning that their cow's milk-based products are known to significantly increase the risk of NEC and death when compared to breast milk in premature infants; and/or
- e. Failing to provide well-researched and well-established studies that linked cow's milk-based products to NEC and death in premature infants; and/or
- f. Failing to insert a warning or instruction to healthcare professionals and

other medical staff in the hospital that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risks; and/or

- g. Failing to provide a warning in a method reasonably calculated/expected to reach the parents of newborns, like the Plaintiff Parent; and/or
- h. Failing to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products.

106. In addition, although Abbott and Mead knew or reasonably should have known at the time of production that their cow's milk-based products significantly increased the risk of NEC, serious injury, and death, they failed to act in a reasonably prudent manner and breached their duty by failing to perform the necessary process of data collection, detection, assessment, monitoring, prevention, and reporting or disclosure of adverse outcomes in infants who ingest their products.

107. As a direct and proximate result of the Defendant Manufacturers' failure to act in a reasonably prudent manner and their breach of duty, the Injured Infant was fed cow's milk-based products, which caused and/or increased the risk of their developing NEC.

108. Had Abbott and Mead satisfied their duties to the consuming public in general, the Injured Infant would not have been exposed to their unreasonably dangerous cow's milk-based products.

109. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers,

individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendants Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT IV: INTENTIONAL MISREPRESENTATION
(Against Abbott and Mead)**

110. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

111. At all times relevant to this action, the Injured Infant consumed the Defendant Manufacturers' products in their intended manner and for their intended purpose.

112. Abbott and Mead, as the manufacturers and/or sellers of the infant products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide truthful, accurate, fulsome information about the risks and benefits of using their products when used in the intended manner and for the intended purpose.

113. Abbott and Mead breached their duty through misrepresentations made to consumers, physicians, and medical staff in their advertising and promotional materials, as described in previous paragraphs and incorporated herein, each of whom were foreseeable and intended recipients of this information.

114. Specifically, upon information and belief, Abbott and Mead made the following false statements of material fact on an ongoing and repeated basis and prior to the time the Injured Infant was fed their products:

- a. That their cow's milk-based products were safe and beneficial for premature infants when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or
- b. That their cow's milk-based products were necessary to the growth and nutrition of premature infants, when they knew or should have known that their products were not necessary to achieve adequate growth; and/or
- c. That their products have no serious side effects, when they knew or should have known the contrary to be true; and/or
- d. That cow's milk-based products were safe for premature infants; and/or
- e. That cow's milk-based products were necessary for optimum growth; and/or
- f. That cow's milk-based products were similar or equivalent to breast milk;

and/or

- g. That their products were safe and more like breast milk than other infant products and that they had removed the harmful ingredients of cow's milk when, in fact, the cow's milk in their products was still capable of causing NEC, serious injury, and death; and/or
- h. That their products were based on up-to-date science, which made them safe for premature infants; and/or
- i. Omitting the material fact that their products significantly increased the risk of NEC in premature infants.

115. Abbott and Mead had actual knowledge, or, at a minimum, a reckless indifference, to whether the aforementioned misrepresentations were false. The Defendant Manufacturers' misrepresentations were intended to, and in fact did, mislead physicians and medical staff, including the Injured Infant's physicians and medical staff, to provide their infant products to babies, including the Injured Infant.

116. The Plaintiff Parent was not aware that these misrepresentations were false and justifiably relied on them. The Defendant Manufacturers' misrepresentations induced the Plaintiff Parent to allow their children to be fed Abbott's and Mead's infant products, in reliance on all the messaging they received about formula feeding, including, directly or indirectly, the Defendant Manufacturers' messaging. Had Abbott and Mead not committed these intentional misrepresentations, the Injured Infant would not have been exposed to the Defendant Manufacturers' unreasonably dangerous cow's milk-based products.

117. As a direct and proximate result, Abbott's and Mead's products were fed to the Injured Infant, which caused and/or increased risk of their developing NEC and subsequent injuries.

118. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT V: NEGLIGENT MISREPRESENTATIONS
(Against Abbott and Mead)**

119. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

120. At all times relevant to this action, the Injured Infant consumed the products at issue in their intended manner and for their intended purpose.

121. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide truthful, accurate, and complete information about the risks and benefits of using their products when used in the intended manner and for the intended purpose.

122. In the course of their business, Abbott and Mead breached their duty through misrepresentations made to consumers, physicians, and medical staff in their advertising and promotional materials, as described in previous paragraphs and incorporated herein, each of whom were foreseeable recipients of this information.

123. Specifically, upon information and belief, Abbott and Mead made the following false statements of material fact on an ongoing and repeated basis and prior to the time the Injured Infant was fed their products:

- a. That their cow's milk-based products were safe and beneficial for premature infants when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or
- b. That their cow's milk-based products were necessary to the growth and nutrition of premature infants, when they knew or should have known that their products were not necessary to achieve adequate growth; and/or
- c. That their products have no serious side effects, when they knew or should

have known the contrary to be true; and/or

- d. That cow's milk-based products were safe for premature infants; and/or
- e. That cow's milk-based products were necessary for optimum growth; and/or
- f. That cow's milk-based products were similar or equivalent to breast milk; and/or
- g. That their products were safe and more like breast milk than other infant products and that they had removed the harmful ingredients of cow's milk when, in fact, the cow's milk in their products was still capable of causing NEC, serious injury, and death; and/or
- h. That their products were based on up-to-date science, which made them safe for premature infants; and/or
- i. Omitting the material fact that their products significantly increased the risk of NEC in premature infants.

124. Abbott and Mead were negligent or careless in not determining those representations to be false.

125. The Defendant Manufacturers' misrepresentations were intended to and did in fact induce physicians and medical staff, including the Injured Infant's physicians and medical staff, to provide their products to babies, including the Injured Infant.

126. The Defendant Manufacturers' misrepresentations induced, and were intended to induce, the Plaintiff Parent to allow their child to be fed Abbott's and Mead's infant products, in justifiable reliance on all the messaging they received about formula feeding, including, directly or indirectly, the Defendant Manufacturers' messaging. Had Abbott and Mead not committed these negligent misrepresentations, the Injured Infant would not have been exposed to their unreasonably

dangerous cow's milk-based products.

127. As a direct and proximate result, Abbott's and Mead's products were fed to the Injured Infant, which caused and/or increased of their developing NEC and subsequent injuries.

128. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection

with this action; and

- g. For such other and further relief as the Court deems proper.

**COUNT VI: FAILURE TO WARN
(Against Penn Medicine and Pennsylvania Hospital)**

129. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

130. Penn Medicine and Pennsylvania Hospital as purchaser, supplier, and/or distributor of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to purchase, supply, and distribute products that were free of unreasonable risk of harm when used in their intended manner and for their intended purpose, and/or to formulate, adopt, and enforce adequate rules and policies for the same.

131. At all times relevant to this action, the Injured Infant used the cow's milk-based products purchased, supplied, and/or distributed by Penn Medicine and Pennsylvania Hospital in their intended manner and for their intended purpose.

132. Penn Medicine and Pennsylvania Hospital employed or contracted with the healthcare professionals and medical staff at Pennsylvania Hospital, managing these individuals during their treatment of the Injured Infant.

133. Penn Medicine and Pennsylvania Hospital negligently, outrageously, and recklessly supplied and distributed the Defendant Manufacturers' milk-based infant feeding products to these healthcare professionals and medical staff for use on premature infants, including the Injured Infant.

134. Moreover, at all relevant times, Penn Medicine and Pennsylvania Hospital knowingly authorized the Defendant Manufacturers' sales representatives to market, advertise, distribute, and/or sell their products at Pennsylvania Hospital. The Defendant Manufacturers' sales

representatives were encouraged to interact with Pennsylvania Hospital's healthcare professionals and medical staff. These interactions provided the Defendant Manufacturers' sales representatives an opportunity to co-opt Pennsylvania Hospital's healthcare professionals and medical staff into assisting with the marketing, distribution, and/or sale of the Defendant Manufacturers' unreasonably dangerous products to consumers, such as the Plaintiff Parent.

135. Penn Medicine and Pennsylvania also knowingly, and intentionally, allowed the Defendant Manufacturers' sales representatives to routinely misrepresent the risks and benefits of Defendants' products to Pennsylvania Hospital's healthcare professionals and medical staff, including the misrepresentation that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

136. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known at the time that they acquired, distributed, and supplied the Defendant Manufacturers' cow's milk-based infant products that these products significantly increased the risk of NEC, serious injury, and death.

137. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, outrageously, and recklessly, and breached its duty by:

- a. Failing to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in those babies; and/or
- b. Failing to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or
- c. Failing to warn or instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice about whether to allow their babies to be fed the Defendant

Manufacturers' products, notwithstanding their substantial risk; and/or

- d. Failing to provide its healthcare professionals and medical staff with the well- researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or
- e. Failing to provide a warning in a method reasonably calculated/expected to reach the parents of newborns; and/or
- f. Failing to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products; and/or
- g. Failing to prevent the Defendant Manufacturers' sales representatives from misrepresenting to Pennsylvania Hospital's healthcare professionals and medical staff that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

138. Reasonable hospitals under the same or similar circumstances would have warned of the above risks, would have instructed their healthcare professionals and medical staff—as well as patients—on the safe use of the Defendant Manufacturers' products, and would have restricted the ability of the Defendant Manufacturers' sales representatives to market the Defendant Manufacturers' unreasonably dangerous products without adequate warning.

139. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that its medical professionals and the parents of premature infants, including the Plaintiff Parent, would not have realized the risks associated with feeding cow's milk-based formula to premature infants.

140. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its

duty to warn its medical providers and patients about the Defendant Manufacturers' unreasonably dangerous products, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

141. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital's failure to warn of the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

142. As a further direct and proximate result of Penn Medicine and Pennsylvania Hospital's failure to warn of the Defendant Manufacturers' unreasonably dangerous products, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against Penn Medicine and Pennsylvania Hospital, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of Penn Medicine's conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational

limit resulting from Penn Medicine and Pennsylvania Hospital's oppressive, outrageous, reckless, and/or malicious conduct, as permitted by law;

- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT VII: CORPORATE LIABILITY OF HEALTH-CARE PROVIDER
(Against Penn Medicine and Pennsylvania Hospital)**

143. Plaintiff incorporates by references each of the preceding paragraphs as if fully set forth herein.

144. At all relevant times, Penn Medicine and Pennsylvania Hospital owed a duty of care to the Injured Infant to ensure their safety and well-being while the Injured Infant was under the care of Pennsylvania Hospital staff. Specifically, Penn Medicine and Pennsylvania Hospital had a duty to the Injured Infant to formulate, adopt, and enforce adequate rules and policies to ensure quality care for the Injured Infant. Further, Penn Medicine and Pennsylvania Hospital owed a duty to the Injured Infant to oversee its healthcare professionals and medical staff that provided patient care to the Injured Infant.

145. Penn Medicine and Pennsylvania Hospital owed a duty to its patients, and the Injured Infant in particular, to formulate, adopt, and enforce adequate rules and policies for the purchase, supply, distribution, and use of products that were free of unreasonable risk of harm when used in their intended manner and for their intended purpose and ensured quality care for the Injured Infant.

146. At all times relevant to this action, the Injured Infant used the cow's milk-based products purchased, supplied, and/or distributed by Penn Medicine and Pennsylvania Hospital in their

intended manner and for their intended purpose.

147. Moreover, at all relevant times, Penn Medicine and Pennsylvania Hospital knowingly authorized the Defendant Manufacturers' sales representatives to market, advertise, distribute, and/or sell their products at Pennsylvania Hospital. The Defendant Manufacturers' sales representatives were encouraged to interact with Pennsylvania Hospital's healthcare professionals and medical staff. These interactions provided the Defendant Manufacturers' sales representatives an opportunity to co-opt Pennsylvania Hospital's healthcare professionals and medical staff into assisting with the marketing, distribution, and/or sale of the Defendant Manufacturers' unreasonably dangerous products.

148. Penn Medicine and Pennsylvania Hospital also knowingly allowed the Defendant Manufacturers' sales representatives to routinely misrepresent the risks and benefits of Defendants' products to Pennsylvania Hospital's healthcare professionals and medical staff, including the misrepresentation that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

149. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known at the time that it formulated, adopted, and enforced its rules for the acquisition, distribution, and supply of the Defendant Manufacturers' cow's milk-based infant products, including the access afforded the Defendant Manufacturer's sales representatives, that these products significantly increased the risk of NEC, serious injury, and death for premature infants.

150. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that its medical professionals and the parents of premature infants, including the Plaintiff Parent, would not have realized the risks associated with feeding cow's milk-based formula to premature infants.

151. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, outrageously,

and recklessly, and breached its duty by:

- a. Failing to formulate, adopt, and enforce adequate rules and policies that would have restricted the use of cow's milk-based products for feeding premature babies; and/or
- b. Failing to formulate, adopt, and enforce adequate rules and policies that warned the Plaintiff Parent that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in premature babies, like the Injured Infant; and/or
- c. Failing to formulate, adopt, and enforce adequate rules and policies that warned its healthcare professionals and medical staff that cow's milk-based products are unsafe and/or contraindicated for premature babies like the Injured Infant; and/or
- d. Failing to formulate, adopt, and enforce adequate rules and policies to instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risk; and/or
- e. Failing to formulate, adopt, and enforce adequate rules and policies to provide its healthcare professionals and medical staff with the well-researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or
- f. Failing to formulate, adopt, and enforce adequate rules and policies to ensure a warning in a method reasonably calculated/expected to reach the

parents of newborns, like the Plaintiff Parent; and/or

- g. Failing to formulate, adopt, and enforce adequate rules and policies to prevent the Defendant Manufacturers' sales representative from misrepresenting to Pennsylvania Hospital's healthcare professionals and medical staff that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants; and/or
- h. Failing to establish a donor milk program that was sufficient to meet the needs of the premature babies, like the Injured Infant.

152. A reasonable hospital under the same or similar circumstances would have formulated, adopted, and enforced adequate policies, and rules to restrict the feeding of cow's milk-based products to premature babies, including developing an adequate donor milk program, instructing its healthcare professionals and medical staff on the safe use of Defendants Manufacturers' cow's milk-based products, and restricting the marketing of the Defendant Manufacturers' unreasonably dangerous products to its healthcare professionals, medical staff, and parents of premature infants under its care.

153. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its duty to formulate, adopt, and enforce adequate rules and policies to ensure the quality care of its patients, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

154. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital failure to formulate and enforce adequate policies and rules related to the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the

Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

155. As a further direct and proximate result of Penn Medicine and Pennsylvania Hospital negligent, reckless, and outrageous conduct the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

156. In the alternative, Penn Medicine and Pennsylvania Hospital owed a duty to its patients, and the Injured Infant in particular, to oversee the practicing healthcare professionals and medical staff that provided the products at issue to infants under Pennsylvania Hospital's care, including the Injured Infant.

157. Penn Medicine and Pennsylvania Hospital employed or contracted with the healthcare professionals and medical staff at Pennsylvania Hospital and was responsible for overseeing those individuals during their treatment of the Injured Infant.

158. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, recklessly, and outrageously breached its duty by:

- a. Failing to oversee its healthcare professionals and medical staff on their use of cow's milk-based products for feeding premature babies; and/or
- b. Failing to warn or instruct its healthcare professionals and medical staff that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in those babies; and/or
- c. Failing to warn or instruct its healthcare professionals and medical staff that cow's milk-based products are unsafe and/or contraindicated for premature babies like the Injured Infant; and/or

- d. Failing to oversee its healthcare professionals and medical staff to restrict their feeding of cow's milk-based products to premature babies; and/or
- e. Failing to warn or instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risk; and/or
- f. Failing to provide its healthcare professionals and medical staff with the well- researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or
- g. Failing to provide its healthcare professionals and medical staff with warnings about the dangers of the Defendants' Manufacturers products in a method reasonably calculated/expected to reach the parents of newborns; and/or
- h. Failing to provide statistical evidence to its healthcare professionals and medical staff showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products; and/or
- i. Failing to oversee its healthcare professionals and medical staff to ensure that the Defendant Manufacturers' sales representatives' misrepresentations that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants had not influenced the use and/or misuse of the Defendant Manufacturers' products.

159. A reasonable hospital under the same or similar circumstances would have warned of the

above risks, would have instructed its healthcare professionals and medical staff on the safe use of the Defendant Manufacturers' products, and would have restricted the ability of the Defendant Manufacturers' sales representatives to market the Defendant Manufacturers' unreasonably dangerous products without adequate warning.

160. A reasonable hospital under the same or similar circumstances would have overseen and managed its healthcare professionals and medical staff to ensure that they received proper training and updating on the risks associated with feeding cow's milk-based formula to premature infants.

161. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its duty to oversee its healthcare professionals and medical staff who provide patient care, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

162. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital's failure to oversee its healthcare professionals and medical staff on the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

163. As a further direct and proximate result of Penn Medicine and Pennsylvania Hospital's negligent and reckless conduct, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against Penn Medicine and Pennsylvania Hospital, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;

- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of Penn Medicine and Pennsylvania Hospital's conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from Penn Medicine's oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

DEMAND FOR JURY TRIAL

164. Plaintiff hereby demands a jury trial for all claims triable.

Dated: 9/8/2023

Respectfully submitted,

KLINE & SPECTER, P.C.

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EXHIBIT D

Alice Stills, on her own behalf and as Parent and Natural
Guardian of M.E., a minor

Plaintiffs

v.

MEAD JOHNSON & COMPANY, LLC, et al.

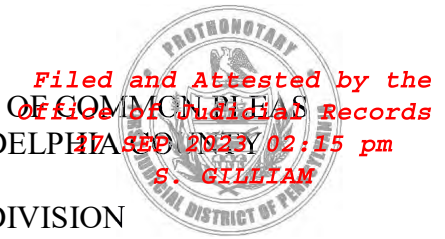
Defendants.

COURT OF COMMON PLEAS
PHILADELPHIA

CIVIL DIVISION

MARCH TERM, 2022

NO. 2617



ORDER

AND NOW, this day of 2023, upon consideration of the Preliminary Objections of Defendants The Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital and The Trustees of the University of Pennsylvania d/b/a Penn Medicine to Plaintiffs' Amended Complaint, and any Response thereto, it is hereby **ORDERED** that the Preliminary Objections are **SUSTAINED**. It is further **ORDERED** that all claims against Defendants the Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital and The Trustees of the University of Pennsylvania d/b/a Penn Medicine are hereby **DISMISSED** with prejudice.

BY THE COURT:

J.

Alice Stills, on her own behalf and as Parent
and Natural Guardian of M.E., a minor

Plaintiffs

v.

MEAD JOHNSON & COMPANY, LLC, et
al.

Defendants.

COURT OF COMMON PLEAS
PHILADELPHIA COUNTY

CIVIL DIVISION

MARCH TERM, 2022
NO. 2617

ALTERNATIVE ORDER

AND NOW, this day of 2023, upon consideration of the Preliminary Objections of Defendants The Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital and The Trustees of the University of Pennsylvania d/b/a Penn Medicine to Plaintiffs' Amended Complaint, and any Response thereto, it is hereby **ORDERED** that the Preliminary Objections are **SUSTAINED**. It is further **ORDERED** that:

1. Count VI of Plaintiffs' Complaint is **DISMISSED** with prejudice;
2. Count VII of Plaintiffs' Complaint is **DISMISSED** with prejudice;
3. Plaintiffs' claims for punitive damages as to Defendants The Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital and The Trustees of the University of Pennsylvania d/b/a Penn Medicine are **DISMISSED** with prejudice, along with all allegations of oppressive, reckless, malicious, outrageous, intentional and/or fraudulent conduct;
4. Plaintiff Holli Carter's claims in her own right are **DISMISSED** with prejudice; and
5. Plaintiffs' Complaint is **STRICKEN** for lack of an appropriate verification.

BY THE COURT:

J.

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Hospital and The Trustees of the University of
Pennsylvania d/b/a Penn Medicine

Alice Stills, on her own behalf and as Parent and
Natural Guardian of M.E., a minor

Plaintiffs

v.

MEAD JOHNSON & COMPANY, LLC, et al.

Defendants.

COURT OF COMMON PLEAS
PHILADELPHIA COUNTY

CIVIL DIVISION

MARCH TERM, 2022
NO. 2617

**PRELIMINARY OBJECTIONS OF DEFENDANTS THE PENNSYLVANIA HOSPITAL
OF THE UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM AND THE
TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA
TO PLAINTIFFS' AMENDED COMPLAINT**

Defendants The Pennsylvania Hospital of the University of Pennsylvania Health System (“Pennsylvania Hospital”) and the Trustees of the University of Pennsylvania (hereinafter “Moving Defendants”) hereby preliminarily object to Plaintiffs’ Amended Complaint, and, in support thereof, aver as follows:

I. INTRODUCTION

1. Plaintiffs instituted this action via the filing of a Complaint on March 24, 2022 against Moving Defendants as well as Co-Defendants Mead Johnson & Company, LLC, Mead Johnson Nutritional Company (collectively referred to as “Mead Johnson”) and Abbott

Laboratories (“Abbott”). See Plaintiffs’ Complaint, attached as Exhibit “A.”¹ On September 8, 2023, Plaintiffs filed an Amended Complaint. See Plaintiffs’ Amended Complaint, attached as Exhibit “B.”

2. Plaintiffs have filed a slew of essentially identical lawsuits against Pennsylvania Hospital and other hospitals in Philadelphia based on claims relating to alleged ingestion of cow’s milk-based infant formula by premature infants following their birth.²

3. Plaintiffs allege that “upon information and belief” the Plaintiff-minors, including M.E., were diagnosed with necrotizing enterocolitis (NEC), a gastrointestinal disorder that premature infants are at increased risk to develop. See Plaintiffs’ Amended Complaint, attached as Exhibit “B,” ¶ 13. Plaintiffs allege that premature infants fed with their mother’s breast milk or donor breast milk are at decreased risk of developing NEC as compared with infants given cow’s milk-based infant formula.³

4. In addition to asserting product liability claims against the infant formula manufacturers Mead Johnson and Abbott, Plaintiffs have alleged that Moving Defendants are liable based on theories of failure to warn and corporate liability.⁴

¹ Shortly after the filing of the Complaint, this case was removed to federal court. Following briefing and a hearing, the case was remanded to this Honorable Court. There was then an effort by all Defendants to transfer these cases to this Court’s Mass Tort Program. Plaintiffs opposed this request, and same was denied by this Honorable Court. These preliminary objections were timely filed after the initial filing of the Complaint, but never ruled upon.

² Lawsuits involving identical claims have been filed against the Hospital of the University of Pennsylvania, Temple University Hospital, Albert Einstein Medical Center and Thomas Jefferson University Hospital.

³ Although Plaintiffs aver in the Amended Complaint that NEC is caused by cow’s milk-based infant formula, as discussed *infra* and in the accompanying Memorandum of Law, Plaintiffs do not cite any study or statement in the Amended Complaint that indicates NEC is caused by cow’s milk-based infant formula.

⁴ As is discussed in detail in the accompanying Memorandum of Law, infant formulas are regulated by the United States Food and Drug Administration and require to include specified vitamins and nutrients, including infant formulas intended for low birth weight infants. The FDA permits does not restrict the use of cow’s milk-based infant formula for premature or low birth weight infants. Plaintiffs’ contention that cow’s milk-based infant formula should never be given to premature infants is not supported by the FDA.

5. The factual background regarding the Plaintiff-minor's birth, diagnosis and injuries are limited to four paragraphs in the Amended Complaint.

6. Plaintiffs aver that M.E. was born prematurely on September 28, 2007 and that "upon information and belief was fed Similac and/or Enfamil cow's milk-based products by staff at Pennsylvania Hospital from shortly after his birth." *Id.*, ¶¶ 11-12.

7. Plaintiffs further allege that "upon information and belief" M.E. developed NEC shortly after first ingesting the Defendant manufacturers' products. *Id.*, ¶ 13.

8. Plaintiffs generally allege that M.E. "suffered injuries, including but not limited to a diagnosis of NEC, treatment with antibiotics and surgery, feeding difficulties, neurological injuries, developmental delays, and growth issues and he continues to suffer other long-term health effects." *Id.*, ¶ 14.

9. Moving Defendants Preliminarily Object to Plaintiffs' Amended Complaint for the reasons stated below and as more fully set forth in the accompanying Memorandum of Law, which is incorporated herein by reference.

II. ARGUMENT

A. DEMURRER TO COUNT VI: FAILURE TO WARN

10. Plaintiffs allege in Count VI of the Amended Complaint that Moving Defendants, "as purchaser, supplier, and/or distributor of the products at issue in the litigation" owed Plaintiffs and the public a duty to provide products that were free of unreasonable risk of harm.

11. Plaintiffs' theory against Moving Defendants is that they were aware cow's milk-based products made by the Defendant Manufacturers cause NEC in premature and low birth weight infants and negligently failed to warn the parents of those infants of this danger.

12. In support of this theory, Plaintiffs simply aver that “(e)xtensive scientific research, including numerous randomized controlled trials, has confirmed that cow’s milk-based feeding products cause NEC in preterm and low-birth-weight infants, which may in turn lead to other medical complications, surgeries, long-term health problems, and death.” *See* Exhibit “B,” ¶16.

13. Taking these facts as pleaded by Plaintiffs as true, Plaintiffs have failed to state a claim for negligent failure to warn against Moving Defendants as they have failed to demonstrate the product in question is indeed unreasonably dangerous.

14. Further, to the extent the product at issue was provided in the context of medical care, rather than commerce, there can be no claim against Moving Defendants for a product-liability based theory of failure to warn.

15. “Pennsylvania has adopted the Restatement (Second) of Torts in cases involving a claim of negligent failure to warn.” *Dauphin Deposit Bank & Trust Co. v. Toyota Motor Corp.*, 596 A.2d 845, 850 (Pa. Super. 1991). Section 388 governs this cause of action, and provides:

One who supplies directly or through a third person a chattel for another to use is subject to liability to those whom the supplier should expect to use the chattel with the consent of the other or to be endangered by its probable use, for physical harm caused by the use of the chattel in the manner for which and by a person for whose use it is supplied, if the supplier

(a) knows or has reason to know that the chattel is or is likely to be dangerous for the use for which it is supplied, and

(b) has no reason to believe that those for whose use the chattel is supplied will realize its dangerous condition, and

(c) fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be dangerous.

Restatement (Second) of Torts § 388.

16. “The threshold inquiry in all products liability cases is whether there is a defect which rendered the product unreasonably dangerous.” *Weiner v. American Honda Motor Co., Inc.*, 718 A.2d 305, 307 (Pa. Super. 1998).

17. “A product is defective when it is not safe for its intended use, i.e., the product left the supplier's control lacking any element necessary to make it safe for its intended use.” *Id.* At 308.

18. Based on the foregoing, Plaintiffs must aver sufficient facts demonstrating the Defendant Manufacturers’ products are unreasonably dangerous for their intended use, triggering Moving Defendants’ duty to warn.

19. Although Plaintiffs vaguely refer in their Amended Complaint to research studies and trials relating to the purported risks of cow’s milk-based products in premature infants, no such studies have been cited for the proposition that feeding premature infants cow’s milk-based formula causes NEC in preterm and low-birth-weight infants.

20. At the outset, Plaintiffs appropriately acknowledge that “[p]reterm and low-birth-weight infants are *especially susceptible to NEC*.” See Exhibit “B” at ¶ 16 (emphasis added). Following this, Plaintiffs make the core claim of their Amended Complaint – that cow’s milk-based feeding products cause NEC in preterm and low birth weight infants – and that “[e]xtensive scientific research, including numerous randomized controlled trials” confirm this claim. *Id.* However, Plaintiffs fail to cite any such research or trials with specificity to support their claim.

21. Simply put, Plaintiffs have failed to state a claim for negligent failure to warn against Moving Defendants as they have failed to state facts to establish that cow’s milk-based infant formula is unreasonably dangerous for its intended purpose.

22. Further, assuming *arguendo* that the Defendant Manufacturers' cow's milk-based feeding products can be seen as unreasonably dangerous for their intended use as opposed to simply being a less effective alternative to breast milk products, Moving Defendants still had no duty to warn of the nature of cow's milk-based products under § 388 because medical providers are not "supplying" a product to a patient within the stream of commerce.

23. Plaintiffs' failure to warn claim is similarly precluded to the extent that Plaintiffs are alleging that Defendants, in providing medical care to Plaintiff-minor, failed to obtain Plaintiff-parent's consent to the use of cow's milk-based products and failed to warn of the purported risks and alternatives of such products.

24. The sole basis upon which Plaintiffs can proceed against Moving Defendants for "failure to warn" in the context of providing medical care is to assert such a claim under a theory of failure to obtain informed consent.

25. Claims for informed consent in medical malpractice actions are governed by the Medical Care Availability and Reduction of Error Act, which provides as follows:

(a) **Duty of Physicians.**--Except in emergencies, a physician owes a duty to a patient to obtain the informed consent of the patient or the patient's authorized representative prior to conducting the following procedures:

- (1) Performing surgery, including the related administration of anesthesia.
- (2) Administering radiation or chemotherapy.
- (3) Administering a blood transfusion.
- (4) Inserting a surgical device or appliance.
- (5) Administering an experimental medication, using an experimental device or using an approved medication or device in an experimental manner.

(b) Description of procedure.--Consent is informed if the patient has been given a description of a procedure set forth in subsection (a) and the risks and alternatives that a reasonably prudent patient would require to make an informed decision as to that procedure. The physician shall be entitled to present evidence of the description of that procedure and those risks and alternatives that a physician acting in accordance with accepted standards of medical practice would provide.

40 P.S. §1303.504 (emphasis added).

26. Since the use of infant formula in feeding premature infants is not a “procedure,” there is no basis for Plaintiffs to contend that Plaintiff-parent’s consent was required for the use of infant formula to feed her infant, including warning her of the risks or alternatives of same.

27. Further, the informed consent statute only applies to physicians, not hospitals, in the context of medical procedures. *See Morgan v. MacPhail*, 550 Pa. 202, 205 (1997).

28. Thus, a hospital cannot be held liable for a physician’s failure to obtain proper informed consent. *Valles v. Albert Einstein Medical Center*, 805 A.2d 1232 (2002).

B. DEMURRER TO COUNT VII: CORPORATE LIABILITY OF HEALTH CARE PROVIDER

29. In *Thompson v. Nason Hospital*, 591 A.2d 703, 708 (Pa. 1991), the Pennsylvania Supreme Court recognized the doctrine of corporate liability, holding that a hospital may be found directly liable for negligence if it fails to meet *any* of the following four duties: (1) a duty to use reasonable care in the maintenance of safe and adequate facilities and equipment; (2) a duty to select and retain only competent physicians; (3) a duty to oversee all persons who practice medicine within its walls as to patient care; and (4) a duty to formulate, adopt and enforce adequate rules and policies to ensure quality care for patients.

30. Plaintiffs’ corporate liability claim fails based on the same rationale as the claim for failure to warn, since both claims are based on the alleged failure to provide warnings to patients related to the use of cow’s milk-based infant formula.

31. Infant formula is regulated by the FDA, and there is no legal restriction on the use of cow's milk-based products for feeding of premature infants.

32. Indeed, the Infant Formula Act expressly acknowledges that it is permissible to provide cow's-milk based products to low birth weight infants.

33. Further, as discussed above, Plaintiffs cannot demonstrate that cow's milk-based formula is an unreasonably dangerous product.

34. Thus, there is no legal basis to contend that Moving Defendants can be held liable pursuant to a theory of corporate liability for failing to prevent the use of cow's milk-based products in the feeding of premature infants in the hospital.

35. Additionally, Courts considering the application of the duties set forth in *Thompson* have insisted on more than a simple finding of a negligent act by someone for whom the hospital is purportedly responsible. *Edwards v. Brandywine Hospital*, 652 A.2d 1382 (Pa. Super. 1995).

36. In considering whether the plaintiff could sustain corporate negligence claims based on these allegations, the *Edwards* court analyzed the Thompson decision and delineated the standards required to sustain such a claim:

The *Thompson* theory of corporate liability **will not be triggered every time something goes wrong in a hospital which harms a patient . . .** To establish corporate negligence, a plaintiff must show more than an act of negligence by an individual for whom the hospital is responsible. Rather, Thompson requires a plaintiff to show that the hospital itself is breaching a duty and is somehow substandard...*Thompson* contemplates a kind of '**systemic negligence**'...

Id. at 1386-87 (citations omitted and emphasis added).

37. Thus, a hospital may not be held liable via corporate negligence simply based on the alleged negligence of an individual health care provider.

38. Accordingly, even if Plaintiffs could establish that the use of cow's milk-based infant formula was a breach of the standard of care by unidentified health care providers based on the

specific circumstances of the Plaintiff-minor's case herein, which has not been pleaded by Plaintiffs considering the paucity of the allegations in the Amended Complaint, such evidence cannot support a finding of corporate liability.

39. Additionally, even assuming Plaintiffs had a viable corporate negligence claim against Pennsylvania Hospital, any such claim is precluded against the Trustees of the University of Pennsylvania since it is not a hospital.

40. The *Thompson* holding has been extended to HMO's and nursing home facilities, where it was determined that such entities performed similar functions as hospitals. *See Shannon v. Health America Pennsylvania, Inc.*, 718 A.2d 828 (Pa. Super. 1998); *Scampone v. Highland Park Care Center, LLC*, 57 A.3d 582 (Pa. 2012).

41. However, courts have routinely refused to extend the *Thompson* holding past such institutions to cover other entities, such as medical clinics and physician practice groups. *See Sutherland v. Monongahela Valley Hospital*, 856 A.2d 55, 62 (Pa. Super. 2004); *Dowhouer v. Judson*, 45 Pa. D. & C.4th 172, 180 (Pa.Com.Pl. 2000); *Brewer v. Geisinger Clinic, Inc.*, 45 Pa. D. & C.4th 215, 223 (Pa.Com.Pl. 2000); *Dibble v. Penn State Geisinger Clinic, Inc.*, 42 Pa. D. & C.4th 225 (Pa.Com.Pl. 1999); *Davis v. Gish*, 5 Pa. D. & C.5th 154, 159 (Pa.Com.Pl. 2007).

42. There is no legal basis for holding that the purported corporate parent of a hospital, such as the Trustees of the University of Pennsylvania, can be held liable under a theory of corporate negligence.

43. Indeed, the *Scampone* Court cautioned that the trial court should ensure that "multiple entities are not exposed to liability for breach of the same non-delegable duties." 57 A.2d at 606-07.

C. MOTION TO STRIKE PLAINTIFFS' COMPLAINT FOR INSUFFICIENT SPECIFICITY AS TO THE FACTS AND ALLEGED INJURIES

44. Pursuant to Pa.R.C.P. 1028(a)(3), a party may file preliminary objections in the nature of a motion to strike for insufficient specificity in a pleading.

45. A plaintiff's Complaint is required to provide a defendant with notice of what the plaintiff's claims are and the grounds upon which they rest, and the complaint must also formulate the issues by summarizing the facts essential to support the claims. *Alpha Tau Omega Fraternity v. The University of Pennsylvania*, 464 A.2d 1349, 1352 (Pa. Super. 1983) (citations omitted).

46. Pennsylvania Rule of Civil Procedure 1019(a) provides that "the material facts on which a cause of action or defense is based shall be stated in a concise and summary form." Pa.R.C.P. 1019(a). As the Superior Court has noted,

Rule 1019(a) requires fact pleading. The purpose of 1019(a) is to require the pleader to disclose the material facts sufficient to enable the adverse party to prepare his case. **A complaint therefore must do more than give the defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests. It should formulate the issues by fully summarizing the material facts. Material facts are ultimate facts, i.e., those facts essential to support the claim. Evidence from which such facts may be inferred not only need not but should not be alleged. Allegations will withstand challenge under 1019(a) if (1) they contain averments of all of the facts a plaintiff will eventually have to prove in order to recover, and (2) they are sufficiently specific so as to enable defendant to prepare his defense.**

Baker v. Rangos, 324 A.2d 498, 505-506 (Pa. Super. 1974) (citations and internal quotations omitted)(emphasis added).

47. Further, it is well established that, with regard to the description of injuries sustained by a plaintiff, the Complaint must be stated with sufficient particularity to put the defendant on notice of evidence that may be produced at trial. *Kelly v. Martino*, 99 A.2d 901 (Pa. 1953). **A plaintiff's Complaint must set forth the extent, nature, location and duration of the injuries suffered, and injuries that are permanent should be stated specifically.** *Miller v.*

Perrige, 71 Pa. D. & C.2d 476, 479–80 (Pa. Com. Pl. 1975). *See, also, Kopan v. Hawk*, 14 Pa. D. & C.2d 713, 714 (Pa. Com. Pl. 1958) (“A catchall averment of “other injuries” is nothing more than a generalized averment under which any injuries whatever could be proved at the trial. Defendant would have no knowledge in advance of the trial of what they are.”)

48. Plaintiffs’ Complaint is woefully deficient with regard to the specificity of the allegations of the relevant facts and injuries at issue in this case.

49. Plaintiffs’ description of the material facts relating to the minor’s care and treatment, diagnosis and injuries is limited to four paragraphs, which are utterly insufficient to enable defendants to prepare their defenses. *See* Exhibit “B,” ¶¶ 11-14.

50. Plaintiffs aver that the minor was born prematurely, the gestational age, and birth weight; however, Plaintiffs’ allegation that “upon information and belief,” the minor was fed Similac and/or Enfamil shortly after his birth (*Id.* at ¶ 12) does not comply with the fact-pleading requirements of Rule 1019(a), since such allegations do not provide defendants with appropriate notice of the facts as to whether the minor actually ingested cow’s milk-based products.

51. Further, Plaintiffs have failed to identify which of the numerous products sold by Abbott and Mead Johnson under the Similac and Enfamil brand names were ingested by the minor.

52. Plaintiffs’ Amended Complaint further fails to provide a description of the material facts as to the period of time in which such products were ingested, when the minor was allegedly diagnosed with NEC and what treatment was provided for that condition.

53. The Amended Complaint further fails to state the nature of the injuries and “long-term health effects” that are alleged to have resulted from the diagnosis of NEC with specificity.

54. Plaintiffs' damages claim is not stated with particularity, is amorphous, vague, and open-ended. Pursuant to Pennsylvania pleading requirements, Moving Defendants should not be compelled to defend a claim for which the statement of injury is unspecified and subject to change.

55. These omissions are fatal defects in Plaintiffs' Amended Complaint. Therefore, Plaintiffs' Amended Complaint should be stricken in its entirety.

D. MOTION TO STRIKE PLAINTIFFS' CLAIMS FOR PUNITIVE DAMAGES

56. In the *Ad Damnum* clauses of Counts VI and VII of the Amended Complaint, Plaintiffs make baseless accusations that Moving Defendants engaged in oppressive, reckless, malicious and/or fraudulent conduct that allegedly justify an award of punitive damages.

57. However, the Complaint contains no specific allegations of conduct that would permit recovery of punitive damages as to Moving Defendants.

58. Rather, Plaintiffs merely allege vaguely that Moving Defendants "negligently, outrageously, and recklessly supplied and distributed the Defendant Manufacturers' milk-based infant feeding products to these healthcare professionals and medical staff for use on premature infants, including the Injured Infant," *See* Exhibit "B" at ¶135, absent any context to indicate that such an action was inappropriate based on the specific issues involved in M.E.'s medical care and condition following birth.

59. For example, the Amended Complaint gives no indication of whether Plaintiff-parent refused or was unable to provide breast milk and provides no information as to discussions between her and any health care providers regarding the purported use of cow's milk-based products.

60. Plaintiffs' allegations of oppressive, malicious and similar conduct must be rejected as mere boilerplate. As discussed above, the FDA specifically approves the use of infant formula

in care of low birth weight infants, with no restriction as to the use of cow's milk-based products for such infants.

61. Indeed, the fact that Plaintiffs have filed numerous lawsuits against at least five hospitals in Philadelphia based on identical claims belies the contention that Moving Defendants engaged in outrageous or malicious conduct in allegedly feeding the Plaintiff-minor with cow's milk-based infant formula.

62. Absent specific factual allegations to justify the claim that the use of infant formula in M.E.'s case was extreme and outrageous, there is no basis for an award of punitive damages in this case.

63. Merely contending that punitive damages should be awarded with no supporting factual justification requires dismissal of the claim.

64. Since the purpose of punitive damages is not compensation of a plaintiff but punishment of the defendant and deterrence, punitive damages can be awarded only for conduct involving some element of outrage. *Hutchinson v. Luddy*, 582 Pa. 114, 870 A.2d 766 (2005). For that reason, Pennsylvania Supreme Court decisions establish that "punitive damages are an 'extreme remedy' available in only the most exceptional matters." *Wagner v. Onofrey*, 2006 Pa. Dist. & Cnty. Dec. LEXIS 333, *11 (Pa. Com. Pl. 2006) (citing *Phillips v. Cricket Lighters*, 584 Pa. 179, 188, 883 A.2d 439, 445 (2005)). "In fact, punitive damages are specifically designed to heap an additional punishment on a defendant who is found to have acted in a fashion which is particularly egregious." *Wagner* at *12.

65. Punitive damages may not be awarded for misconduct that constitutes ordinary negligence such as inadvertence, mistake and errors of judgment. *Martin v. Johns-Manville Corp.*, 494 A.2d 1088, 1097 (Pa. 1985); *McDaniel v. Merck, Sharp & Dohme*, 533 A.2d 436, 437 (Pa.

Super. 1987). An award of punitive damages must be supported by evidence of conduct more serious than the mere commission of the underlying tort. *Allstate Ins. Co. v. A.M. Pugh Assoc., Inc.*, 604 F. Supp. 85, 99 (M.D. Pa. 1984).

66. Specifically, with regard to punitive damages in the context of claims against health care providers, the Medical Care and Reduction of Error (MCARE) Act permits punitive damages only to be awarded as follows:

(a) Award. -- Punitive damages may be awarded for conduct that is the result of the health care provider's willful or wanton conduct or reckless indifference to the rights of others. In assessing punitive damages, the trier of fact can properly consider the character of the health care provider's act, the nature and extent of the harm to the patient that the health care provider caused or intended to cause and the wealth of the health care provider.

(b) Gross Negligence. -- A showing of gross negligence is insufficient to support an award of punitive damages.

40 P.S. §1303.505.

67. The Supreme Court has made clear that when assessing the propriety of the imposition of punitive damages, "the state of mind of the actor is vital. The act or failure to act, must be intentional, reckless or malicious." *Hutchinson, supra* at 770. An appreciation of the risk is a necessary element of the mental state required for the imposition of punitive damages. *Id.* at 772.

68. Thus, "a punitive damages claim must be supported by evidence sufficient to establish that (1) a defendant had a subjective appreciation of the risk of harm to which the plaintiff was exposed and that (2) he acted, or failed to act, as the case may be, in conscious disregard of that risk." *Id.*

69. Since professional negligence actions involve allegations that health care professionals deviated from the governing standard of care, punitive damages are generally not

recoverable in malpractice actions unless the medical provider's deviation from the applicable standard of care is so egregious as to evince a conscious or reckless disregard of a patent risk of harm to the patient. *Wagner, supra*.

70. Where the facts as averred show nothing more than negligence, a lapse in judgment, or mere inadvertence, courts in Pennsylvania have dismissed pleas and claims for punitive damages, often at the pleadings stage of litigation and even if the complaint alleged severe injuries or death. *See, e.g., Brownawell v. Bryan*, 40 Pa. D. & C.3d 604, 606 (Pa. Com. Pl. 1985) (dismissing punitive damages claim where a plaintiff alleged that a physician negligently performed a spinal fusion surgery that left the plaintiff with severe neurological defects, and noting that “**the mere pleading of outrageous conduct** does not, of course, satisfy the requirement stating facts which, if proven, would form a basis for a jury concluding that the conduct was such that an award of punitive damages was warranted.”) (emphasis added); *Wagner, supra* at *11 (contentions that physician failed to prescribe antibiotics, order certain tests or request an infectious disease consult constituted “nothing more than ordinary negligence and are insufficient to support an award of punitive damages.”); *McCardle v. Aldinger*, 5 Pa. D. & C.4th 421, 428 (Pa. Com. Pl. 1996) (sustaining preliminary objections and dismissing claim for punitive damages where the plaintiff alleged negligence in the prenatal care of her child that led to the child was stillborn and holding that “[i]t is not the outcome of the alleged negligence that is of consideration, but rather the alleged conduct of defendants that is at issue.”); *Flurer v. Pocono Medical Ctr.*, 15 Pa. D. & C.4th 645, 670 (Pa. Com. Pl. 1992) (sustaining preliminary objections and finding that plaintiffs were not “capable of pleading the requisite behavior” for an award of punitive damages where a hospital allegedly failed to properly utilize a fetal monitor on a pregnant woman who was involved in a serious car accident and thereafter delivered a stillborn child).

71. Conversely, punitive damages have been reserved for those situations that are truly egregious and utterly outrageous, and typically involve aggravating or other factors that evince a particularly reckless mind or evil motive. *See, e.g., Medvecz v. Choi*, 569 F.2d 1221, 1227-30 (3rd Cir. 1987) (anesthesiologist who abandoned patient on operating room table and left room for a lunch break without securing a suitable replacement could be liable for punitive damages to patient who suffered irreversible paralysis from anesthesia complication that developed during his absence); *Hoffman v. Memorial Osteopathic Hospital*, 492 A.2d 1382, 386-87 (Pa. Super. 1985) (evidence that emergency room physician allowed Guillain-Barre Syndrome patient suffering from neurological paralysis to remain crying and immobile on floor for two hours as physician repeatedly stepped over patient was sufficient to support punitive damages claim); *Guernsey v. County Living Personal Care Home, Inc.*, 2006 U.S. Dist. LEXIS 31450, 2006 WL 1412765 (M.D. Pa. 2006) (punitive damages recoverable from nursing home officials who allowed resident to have access to room of 86-year old Alzheimer's patient where he repeatedly raped her, since nursing home was aware of resident's prior criminal convictions for sex registration as a sexual offender under Megan's Law, and his prior instances of grabbing and kissing staff); *Lawrence v. Kunkle*, 75 D. & C. 4th 370 (Pa. Com. Pl. 2005) (patient could maintain punitive damages claim against physician who refused to perform emergency surgery because patient did not have medical insurance even though physician knew that patient would likely suffer permanent neurologic and functional deficits if surgery was delayed).

72. The facts underlying Plaintiffs' bare assertions of reckless, outrageous or similar behavior do not even remotely meet the requisite standard under Pennsylvania law that would permit an award of punitive damages.

73. Additionally, pursuant to § 505(c) of the MCARE Act, punitive damages are specifically restricted in claims involving vicarious liability:

(c) Vicarious liability. -- Punitive damages shall not be awarded against a healthcare provider who is only vicariously liable for the actions of its agent that caused the injury unless it can be shown by a preponderance of the evidence that the party knew of and allowed the conduct of its agent that resulted in an award of punitive damages.

40 P.S. §1303.505(c).

74. Plaintiffs allege in this action that unidentified “staff” fed M.E. Similac and/or Enfamil at Pennsylvania Hospital shortly after his birth and failed to warn Plaintiff-parent of the alleged risks of such products. See Exhibit “B,” ¶ 12.

75. Even if such actions were claimed to be egregious or malicious such that punitive damages were permissible, which is denied for the reasons stated above, Plaintiffs must allege facts to establish that Moving Defendants had actual knowledge of the alleged wrongful conduct and nevertheless allowed it. *See Zazzera v. Roche*, 54 D. & C. 4th 225, 238 (Pa. Com. Pl. 2001); *Dean Witter Reynolds, Inc. v. Genteel*, 499 A.2d 637 (Pa. Super. 1985).

76. In this matter, Plaintiffs have failed to plead any facts to suggest that Moving Defendants were aware of any alleged misconduct by any individual alleged to be an agent and allowed such conduct to continue.

77. For all these reasons, Plaintiffs’ demand for punitive damages must be stricken with prejudice as to Moving Defendants, along with all allegations of reckless and similar conduct.

E. MOTION TO DISMISS PLAINTIFF-PARENT’S CLAIMS

78. Plaintiff-parent seeks to recover damages in her own right and as the parent and natural guardian of M.E.

79. Plaintiffs' Amended Complaint includes allegations in each count asserted as to Moving Defendants in which it is averred that Plaintiff-parent "suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly altered by the Injured Infant's injuries." *See* Exhibit "B," ¶¶ 142, and 163.

80. However, no specific cause of action is asserted as to any damages sought on behalf of Plaintiff-parent, who is not alleged in the Amended Complaint to have suffered any physical injuries as a result of the alleged negligent conduct of Moving Defendants. For this reason, Plaintiff-parent's claim should be dismissed.

81. Further, even if Plaintiff-parent had properly articulated a cause of action in the Complaint to allow her to recover damages in her own right, the Complaint should be stricken pursuant to Pa.R.C.P. 1020(b), which provides as follows:

If persons join as plaintiffs under Rules 2228, 2229(a) or (e), the complaint shall state the cause of action, any special damage, and the demand for relief of each plaintiff in a separate count, preceded by a heading naming the parties to the causes of action therein set forth.

82. Accordingly, it is improper for Plaintiffs to plead in a single count claims on behalf of both the Plaintiff-minor and the Plaintiff-parent, as was done in the Amended Complaint filed herein. Claims on behalf of each of the Plaintiffs must be set forth in separate counts of the Complaint, specifically identifying the cause of action asserted and relief sought in each count.

83. Additionally, although the statute of limitations for claims asserted on behalf of minors are tolled until the age of majority, Plaintiff-parent's claims were not similarly tolled and were required to have been brought within two years of the alleged injury. *See Hathi v. Krewstown Park Apts*, 561 A.2d 1261 (Pa. Super. 1989); 42 Pa.C.S. § 5524.

84. Plaintiffs allege that M.E. was born on September 28, 2007, was fed the Defendant manufacturers' products shortly after his birth, and developed NEC shortly thereafter. *See* Exhibit "B," ¶¶ 11-13.

85. Thus, since the Complaint herein was filed on March 24, 2022, Plaintiff-parent's claims herein are clearly time-barred based on the applicable statute of limitations.

86. In an attempt to circumvent the statute of limitations issues for the Plaintiff-parent, Plaintiffs go to great lengths in their Amended Complaint to essentially assert that Plaintiff-parent's claims are somehow preserved by way of the discovery rule. *See*, Exhibit "B" ¶¶ 23 – 41.

87. However, it is well established in Pennsylvania that a plaintiff need not know the precise extent of injuries before the statutory period begins to run. *Levenson v. Souser*, 384 Pa. Super. 132, 557 A.2d 1081, 1090 (1989).

88. Furthermore, any contention by Plaintiffs that the statute of limitations must be tolled until such time that a plaintiff first suspected that there had been medical negligence with regard to her infant's treatment must similarly be rejected.

89. It is well settled law that, in accordance with the discovery rule, a plaintiff need not know that she has a cause of action or suspects there has been negligence before the statute of limitations commences. *Colonna v. Rice*, 664 A.2d 979, 981 (Pa. Super. 1995); *Bigansky v. Thomas Jefferson Univ. Hosp.*, 658 A.2d 423, 427, 431 n.5 (Pa. Super. 1995); *Brooks v. Sagovia*, 636 A.2d 1201, 1204 (Pa. Super. 1994); *E.J.M. v. Archdiocese of Phila.*, 622 A.2d 1388, 1394 (Pa. Super. 1993); *DeMartino v. Albert Einstein Med. Center*, 460 A.2d 295, 298-299 (Pa. Super. 1983).

90. Indeed, it has been expressly held that "[k]nowledge of the negligence is not part of the discovery rule." *DeMartino, supra*, 460 A.2d at 299.

91. A plaintiff need only know that there was an injury and who caused that injury, a plaintiff need not know the full extent of the injury or even suspect negligence. *Nicolaou v. Martin*, 195 A.3d 880, 892-93 (Pa. 2018); *Gleason v. Borough of Moosic*, 15 A.3d 479, 484 (Pa. 2011); *Wilson v. El-Daief*, 964 A.2d 354, 364 (Pa. 2009).

92. Based upon the facts plead by Plaintiffs, M.E. is alleged to have developed NEC shortly after his birth. See Exhibit “B” ¶¶11 – 14. Accordingly, Plaintiff-parent knew of an injury in 2007, making any claim in her own right clearly time barred, regardless of whether she knew the extent of any claimed injury and/or when she suspected that the injury was caused by negligence.

F. MOTION TO STRIKE PLAINTIFFS’ COMPLAINT FOR FAILURE TO COMPLY WITH Pa.R.C.P. 1024

93. Pennsylvania Rule of Civil Procedure 1024(a) requires verification of every pleading containing a factual averment based upon the signer’s personal knowledge or information and belief.


94. Rule 1024(c) requires that the verification be made by one or more of the parties filing the pleading.

95. In this case, no verification is attached to the Amended Complaint in violation of Rule 1024. See Exhibit “B.”

96. Accordingly, the Amended Complaint should be stricken for lack of an appropriate verification.

WHEREFORE, Defendants The Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital and The Trustees of the University of Pennsylvania d/b/a Penn Medicine respectfully request that this Honorable Court sustain the instant Preliminary Objections and enter the attached proposed Order.

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Guardian of M.E., a minor

Plaintiffs

v.

MEAD JOHNSON & COMPANY, LLC, et al.

Defendants.

COURT OF COMMON PLEAS
PHILADELPHIA COUNTY

CIVIL DIVISION

MARCH TERM, 2022
NO. 2617

**MEMORANDUM OF LAW IN SUPPORT OF PRELIMINARY OBJECTIONS OF
DEFENDANTS THE PENNSYLVANIA HOSPITAL OF THE UNIVERSITY OF
PENNSYLVANIA HEALTH SYSTEM AND THE TRUSTEES OF THE UNIVERSITY
OF PENNSYLVANIA TO PLAINTIFFS' COMPLAINT**

I. MATTER BEFORE THE COURT

Preliminary Objections of Defendants The Pennsylvania Hospital of the University of Pennsylvania Health System ("Pennsylvania Hospital") and The Trustees of the University of Pennsylvania to Plaintiffs' Amended Complaint.

While patently obvious that Plaintiffs' Amended Complaint must be dismissed for clear and important violations of the procedural requirements governing pleadings and verification of the accuracy of the factual averments of the Amended Complaint (there are not separate counts identified for the causes of action of each of the Plaintiffs attempts to allege), most of which are averred "upon information and belief," the substance of Plaintiffs' allegations do not support any legally recognized cause of action against Moving Defendants, under Pennsylvania law. Our

procedural rules do not permit a plaintiff to simply identify allegedly tortious conduct by a defendant without pleading the necessary facts to satisfy the elements of the tortious conduct.

Here, Plaintiffs plead that Moving Defendants permitted Co-Defendants' cow's milk-based infant formula to be fed to prematurely born infants, which allegedly caused those infants to develop necrotizing enterocolitis ("NEC"). Plaintiffs then plead themselves out of Court by attempting to support a "failure to warn" claim by referencing unnamed studies and trials in an attempt to establish that cow's milk-based infant formulas cause NEC. Thus, distinct from the Amended Complaint's procedural shortcomings, Plaintiffs have failed to plead facts that support the "failure to warn" and corporate liability causes of action that they attempt to assert against Moving Defendants. It is further noteworthy that there is no viable "failure to warn" cause of action that is recognized under Pennsylvania law against Moving Defendants, as explained in this submission by Moving Defendants.

II. STATEMENT OF QUESTIONS PRESENTED

1. Whether this Honorable Court should dismiss Count VI of Plaintiffs' Amended Complaint "Failure to Warn" cause of action with prejudice because Plaintiffs' Amended Complaint does not support the claim that cow's milk-based products are unreasonably dangerous and Moving Defendants cannot be held liable for negligent failure to warn on the basis that they are a supplier of such products?

Suggested answer in the affirmative.

2. Whether this Honorable Court should dismiss Count VI of Plaintiffs' Amended Complaint "Failure to Warn" cause of action with prejudice because it improperly alleges that Moving Defendants were required to obtain Plaintiff-parent's informed consent to use of cow's

milk-based products for feeding of Plaintiff-minor and warn her of the risks and/or alternatives of same?

Suggested answer in the affirmative.

3. Whether this Honorable Court should dismiss Count VII of Plaintiffs' Amended Complaint "Corporate Negligence" cause of action with prejudice because Moving Defendants cannot be held liable on such a theory for a product which is regulated by the FDA and which is not precluded for use in premature or low birth weight infants, and where a hospital cannot be held liable for corporate negligence based on the alleged negligence of an individual health care provider?

Suggested answer in the affirmative.

4. Whether this Honorable Court should dismiss Count VII of Plaintiffs' Amended Complaint "Corporate Negligence" cause of action with prejudice as to the Trustees of the University of Pennsylvania since it is not a hospital and because corporate negligence duties are non-delegable?

Suggested answer in the affirmative.

5. Whether this Honorable Court should strike Plaintiffs' Amended Complaint in its entirety for insufficient specificity of the facts and alleged injuries?

Suggested answer in the affirmative.

6. Whether this Honorable Court should strike Plaintiffs' claims for punitive damages as to Moving Defendants because the Amended Complaint fails to plead facts providing a basis for an award of punitive damages?

Suggested answer in the affirmative.

7. Whether this Honorable Court should strike Plaintiff-parent's claims for failure to state a cause of action, and for failure to plead separate causes of action pursuant to Pa.R.C.P. 1020 and based on the applicable statute of limitations?

Suggested answer in the affirmative.

8. Whether this Honorable Court should strike Plaintiffs' Amended Complaint for failure to provide a client verification as required by Pa.R.C.P. 1024?

Suggested answer in the affirmative.

III. INTRODUCTION AND FACTUAL BACKGROUND

Plaintiffs have filed a slew of essentially identical lawsuits against Pennsylvania Hospital and other hospitals in Philadelphia based on claims relating to alleged ingestion of cow's milk-based products by premature infants in the hospital following their birth.¹ Plaintiffs allege that the Plaintiff-minors, including M.E., were diagnosed with necrotizing enterocolitis (NEC), a gastrointestinal disorder that premature infants are at increased risk to develop. *See* Plaintiffs' Amended Complaint, attached as Exhibit "B" at ¶ 14. Plaintiffs aver that premature infants fed with their mother's breast milk or donor breast milk are at decreased risk of developing NEC as compared with infants given cow's milk-based products (infant formula). Many of the allegations of the Complaint are pleaded "upon information and belief," including the allegations that Plaintiff-minors received infant formula and that they developed NEC shortly after being fed with infant formula.

In addition to asserting product liability claims against the infant formula manufacturers Mead Johnson & Company, LLC, Mead Johnson Nutritional Company (collectively referred to as

¹ Lawsuits involving identical claims have been filed against the Hospital of the University of Pennsylvania, Temple University Hospital, Albert Einstein Medical Center and Thomas Jefferson University Hospital.

“Mead Johnson”) and Abbott Laboratories (“Abbott”)², Plaintiffs have alleged that Moving Defendants are liable based on theories of failure to warn and corporate liability. *See* Plaintiffs’ Amended Complaint, attached as Exhibit “B” at Counts VI and VII. As is discussed in detail below, Plaintiffs’ claims against Moving Defendants are legally and factually deficient.

Although Plaintiffs baldly aver that NEC is caused by cow’s milk-based products, Plaintiffs refer in their Amended Complaint only to research studies and trials with no specificity whatsoever. As discussed in detail *supra*, even assuming the truth of the factual allegations stated in Plaintiffs’ Amended Complaint, Plaintiffs’ allegations do not support the conclusion that NEC is caused by cow’s milk-based products. As such, there is no basis to contend that cow’s milk-based products are dangerous for premature infants, such that Moving Defendants had a duty to warn Plaintiff-parents of any risks or alternatives related to infant formula.

Plaintiffs’ Complaint provides scant information regarding the factual background of this case. Plaintiffs aver that M.E. was born prematurely on September 28, 2007 and that “upon information and belief was fed Similac and/or Enfamil cow’s milk-based products by staff at Pennsylvania Hospital from shortly after his birth.” *Id.*, ¶¶ 11-12. Plaintiffs further allege that “upon information and belief” M.E. developed NEC shortly after first ingesting the Defendant manufacturers’ products. *Id.*, ¶ 13. No specific details are provided regarding the infant’s condition following birth other than that he developed NEC on an unidentified date, that he was treated with antibiotics and surgery, and suffered from feeding difficulties, unspecified neurological injuries, unspecified developmental delays and growth issues, and continues to suffer other unspecified long-term health effects. *Id.* at ¶14. No specific facts are provided by Plaintiffs as to any medical care M.E. received, for what period of time M.E. allegedly ingested cow’s milk-based products,

² Mead Johnson and Abbott have been the subject of similar lawsuits in other states, including Connecticut, Illinois and California.

and which product(s) he allegedly ingested.³ Finally, the Amended Complaint is silent as to the nature and extent of M.E.'s alleged injuries other than a vague reference to nonspecific injuries and long term health effects. *Id.* ¶ 14.

Further, the Amended Complaint does not provide any details whatsoever regarding communications between Plaintiff-parent and medical providers at Pennsylvania Hospital regarding the allegations that M.E. may have been fed with Mead Johnson and/or Abbott cow's milk-based products in the hospital. Plaintiffs do not provide any information regarding discussions between Plaintiff-parent and any health care providers at Pennsylvania Hospital related to breastfeeding and/or using cow's milk-based products in this case, including whether or not she was encouraged to breastfeed and/or was unable or declined to do so. As noted, Plaintiffs plead that Plaintiff Minor ingested formula "on information and belief" only, and similarly plead "on information and belief" that Plaintiff Minor developed NEC as a result.

Plaintiffs further fail to disclose in their Complaint that infant formula is regulated by the United States Food and Drug Administration (FDA) and that there is no restriction on the use of cow's milk-based products for premature infants. The federal Infant Formula Act of 1980 ("IFA") was enacted "to assure the safety and nutrition of infant formulas." Pub. L. No. 96-359, 94 Stat. 1190. The IFA and its implementing regulations outline the requirements that infant formula must meet, including how infant formula is made, its contents and ingredients, and the labels used on its packages. 21 U.S.C. § 350a; 21 C.F.R. §§ 106-07. The IFA provides that infant formulas may only contain "substances that are safe and suitable for use in infant formula." 21 C.F.R. § 106.40(a). Neither the IFA nor the regulations exclude cow milk as an ingredient, and many infant formulas

³ Plaintiffs aver that Abbott sells at least seven types of products directed to preterm and/or low birth weight infants, six of which use the name Similac, and that Mead Johnson sells eight types of infant formulas using the Enfamil brand name. *Id.*, ¶¶ 48, 49.

for sale include cow milk; 21 C.F.R. § 106.3 (“infant formula” is a “food for infants by reason of its *simulation* of human milk”) (emphasis added). 21 U.S.C. § 350a; 21 C.F.R. §§ 107.50. Before selling any “new infant formula,” a manufacturer must (1) register with the FDA, and (2) submit a notice to the FDA at least 90 days before marketing such formula. The notice must also state that the formula contains the required vitamins and nutrients, as demonstrated by testing. 21 U.S.C. § 350a(b). These same FDA review procedures apply when a manufacturer makes a “major change” to an existing formula. 21 U.S.C. § 350a(c)(2)(B); 21 C.F.R. § 106.3.

Further, the FDA recognizes that certain infant formulas are intended for low birth weight babies (such as infants born prematurely) or infants with unusual medical or dietary problems. Indeed, such formulas have special review requirements. 21 U.S.C. § 350a(h); 21 C.F.R. § 107.50(a). For those formulas – known as “exempt” formulas because they may be exempted from certain requirements – the required 90-day notice must include “the label and other labeling of the infant formula, a complete quantitative formulation for the infant formula, and a detailed description of the medical conditions for which the infant formula is represented.” 21 C.F.R. § 107.50(b)(3). As with other formulas, the regulations do not exclude cow milk as an ingredient for infant formulas intended for use by an infant with a low birth weight.

Thus, since Plaintiffs do not allege that the product did not meet federal requirements, there is no basis for any claim that the product is unreasonably dangerous and/or should not be given under any circumstances to premature or low birth weight infants.

IV. ARGUMENT

A. DEMURRER TO COUNT VI: FAILURE TO WARN

1. Moving Defendants Cannot Be Held Liable to Plaintiffs Based on a Theory of Failure to Warn Because the Infant Formula is Not Unreasonably Dangerous

Pursuant to Pa.R.C.P. 1028(a)(4), a party may file preliminary objections to a complaint, in the nature of a demurrer, for legal insufficiency in a pleading. A court should grant a demurrer where, accepting as true all well pled facts, a legal cause of action cannot be maintained upon those facts. Pa.R.C.P. 1028(a)(4); *See also, Willet v. Pennsylvania Med. Catastrophe Loss Fund*, 702 A.2d 850, 853 (Pa. 1997).

Plaintiffs allege in Count VI of the Amended Complaint that Moving Defendants, “as purchaser, supplier, and/or distributor of the products at issue in the litigation” owed Plaintiffs and the public a duty to provide products that were free of unreasonable risk of harm. Plaintiffs’ theory against Moving Defendants is that they were aware cow’s milk-based products manufactured by Mead Johnson and Abbott cause NEC in premature and low birth weight infants and negligently failed to warn the parents of those infants of this danger. However, Plaintiffs do not cite any study or statement in the Amended Complaint that indicates that NEC is caused by cow’s milk-based infant formula. Taking the facts as pleaded by Plaintiffs as true, Plaintiffs have failed to state a claim for negligent failure to warn against Moving Defendants as they have failed to demonstrate the products in question are indeed unreasonably dangerous. Further, to the extent the product at issue was provided in the context of medical care, rather than commerce, there can be no claim against Moving Defendants for a product-liability based theory of failure to warn.

“Pennsylvania has adopted the Restatement (Second) of Torts in cases involving a claim of negligent failure to warn.” *Dauphin Deposit Bank & Trust Co. v. Toyota Motor Corp.*, 596 A.2d 845, 850 (Pa. Super. 1991). Section 388 governs this cause of action, and provides:

One who supplies directly or through a third person a chattel for another to use is subject to liability to those whom the supplier should expect to use the chattel with the consent of the other or to be endangered by its probable use, for physical harm caused by the use of the chattel in the manner for which and by a person for whose use it is supplied, if the supplier

- (a) knows or has reason to know that the chattel is or is likely to be dangerous for the use for which it is supplied, and
- (b) has no reason to believe that those for whose use the chattel is supplied will realize its dangerous condition, and
- (c) fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be dangerous.

Restatement (Second) of Torts § 388. To survive preliminary objections, Plaintiffs must aver sufficient facts, together with the documents and exhibits attached thereto, to make out a *prima facie* case as to all elements of the cause of action. *Northern Forests II, Inc. v. Keta Realty Co.*, 130 A.3d 19, 35 (Pa. Super. 2015).

“The threshold inquiry in all products liability cases is whether there is a defect which rendered the product unreasonably dangerous.” *Weiner v. American Honda Motor Co., Inc.*, 718 A.2d 305, 307 (Pa. Super. 1998). “A product is defective when it is not safe for its intended use, i.e., the product left the supplier's control lacking any element necessary to make it safe for its intended use.” *Id.* At 308. Whether a product is “unreasonably dangerous” is a question of law. *Id.* Based on the foregoing, Plaintiffs must aver sufficient facts demonstrating the Defendant Manufacturers’ products are unreasonably dangerous for their intended use, triggering Moving Defendants’ duty to warn. They have not done so as the studies they cite in their Complaint do not

say – based on the very allegations in the Complaint - what Plaintiffs claim they do. Therefore, Moving Defendants had no corresponding duty to warn.

At the outset, Plaintiffs appropriately acknowledge that “[p]reterm and low-birth-weight infants are *especially susceptible to NEC*.” See Exhibit “B” at ¶ 16 (emphasis added). Following this, Plaintiffs make the core claim of their Complaint – that cow’s milk-based feeding products cause NEC in preterm and low birth weight infants – a claim that is unsupported by any specific studies or trials in the Amended Complaint. *Id.* Admittedly, if a product directly causes NEC in preterm and low birth weight infants, that product would certainly be dangerous. However, Plaintiffs’ Amended Complaint does nothing to support this bald allegation.

Ultimately, Plaintiffs’ claim that Defendant Manufacturers’ cow’s milk-based feeding products cause NEC and are therefore unreasonably dangerous rests upon the notion that correlation equals causation. However, Plaintiffs have not, and cannot, establish causation. Plaintiffs readily admit at paragraph 16 of the Amended Complaint that preterm and low-birth-weight infants are especially susceptible to NEC because of their underdeveloped digestive systems. All that Plaintiffs’ Amended Complaint demonstrates, as pleaded under these facts, is that breast milk may be better at reducing that already high risk of NEC in these infants than cow’s milk-based alternatives. This proposition does not make the Defendant Manufacturers’ cow’s milk-based alternatives unreasonably dangerous within the meaning of § 388 of the Restatement (Second) of Torts and, accordingly, does not trigger a duty to warn on the part of Moving Defendants.

2. Moving Defendants Are Not a “Supplier” and, Therefore, Cannot Be Held Liable for Negligent Failure to Warn

Assuming *arguendo* that the Defendant Manufacturers’ cow’s milk-based feeding products can be seen as dangerous for their intended use as opposed to simply being a less effective

alternative to breast milk products, Moving Defendants still had no duty to warn of the nature of cow's milk-based products under § 388 because they are not considered a supplier of cow's milk-based feeding products. Plaintiffs cite to no caselaw in Pennsylvania holding that a hospital is considered a supplier under § 388. Indeed, extensive research into this topic turns up no prior decisions where a Pennsylvania court has found a hospital to be a supplier in a products liability case for negligent failure to warn.

To determine a hospital may be defined as supplier of products ancillary to and following medical services within the meaning of § 388 would be to impose on the hospital a duty to warn about every conceivable object a patient may encounter in a hospital, right down to the napkins available in the hospital cafeteria. Imposing such a duty does nothing to advance the purpose of products liability law, i.e. to protect consumers from dangerous products in the stream of commerce. Moving Defendants are not in the best position to determine what products are available in the market for premature and low weight birth infants. In light of this, Plaintiffs have not sufficiently pleaded that Moving Defendants are a supplier under § 388.

For the foregoing reasons, Plaintiffs have not pleaded sufficient facts to aver the Defendant Manufacturers' products are unreasonably dangerous for their intended use and thus have not established Moving Defendants had a duty to warn. Alternatively, even if the products at issue here can be viewed as unreasonably dangerous, Plaintiffs still have failed to plead sufficient facts that Moving Defendants are a supplier of products that are ancillary to the medical services provided to Plaintiffs. Accordingly, it is respectfully requested this Court sustain Moving Defendants' Preliminary Objections to Count VI: Failure to Warn of Plaintiffs' Amended Complaint.

3. There is no Legal Basis for Plaintiffs to Present an Informed Consent Claim Regarding the Use of Cow's milk-based products

Plaintiffs' failure to warn claim is couched in language of product liability related to Moving Defendants' alleged duty "as a purchaser, supplier and/or distributor" to provide a product (cow's milk-based infant formula) that was free of unreasonable risk of harm to consumers (parents and their premature infants). This theory fails for the reasons stated above. However, to the extent that Plaintiffs are alleging that Moving Defendants, in providing medical care to Plaintiff-minor, failed to obtain Plaintiff-parent's consent to the use of cow's milk-based products and failed to warn of the purported risks and alternatives of such products, such a claim is also clearly precluded by Pennsylvania law.

Plaintiffs broadly allege that Moving Defendants failed to warn of the alleged dangers of cow's milk-based products and provide them with information necessary "to make an informed choice about whether to allow their baby to be fed the Defendant Manufacturers' products." *See* Exhibit "B" at ¶ 137. This purported failure to warn/inform allegedly led Plaintiff-minor to be fed a cow's milk-based product that Plaintiffs' contend caused and/or increased the risk of NEC. *Id.* at ¶ 141. The sole basis upon which Plaintiffs can proceed against Moving Defendants for "failure to warn" in the context of providing medical care is to assert such a claim under a theory of failure to obtain informed consent. Plaintiffs are impliedly asserting that Moving Defendants failed to obtain Plaintiff-parent's informed consent as to whether she should use cow's milk-based infant formula to feed her child as opposed to breastfeeding or using breast donor milk, based on the alleged risks of cow's milk-based products. However, such a claim is not cognizable under Pennsylvania law.

Claims for informed consent in medical malpractice actions are governed by the Medical Care Availability and Reduction of Error Act, which provides as follows:

(a) **Duty of Physicians.**--Except in emergencies, a physician owes a duty to a patient to obtain the informed consent of the patient or the patient's authorized representative prior to conducting the following procedures:

- (1) Performing surgery, including the related administration of anesthesia.
- (2) Administering radiation or chemotherapy.
- (3) Administering a blood transfusion.
- (4) Inserting a surgical device or appliance.
- (5) Administering an experimental medication, using an experimental device or using an approved medication or device in an experimental manner.

(b) Description of procedure.--Consent is informed if the patient has been given a description of a procedure set forth in subsection (a) and the risks and alternatives that a reasonably prudent patient would require to make an informed decision as to that procedure. The physician shall be entitled to present evidence of the description of that procedure and those risks and alternatives that a physician acting in accordance with accepted standards of medical practice would provide.

40 P.S. §1303.504 (emphasis added).

The clear language of the statute above reveals two significant tenets. The first is that the informed consent statute does not apply to the use of infant formula in feeding premature infants, since that is not a "procedure." Thus, there is no basis for Plaintiffs to contend that Plaintiff-parent's consent was required for the use of infant formula to feed her infant, including warning her of the risks or alternatives of same. Second, the informed consent statute only applies to physicians, not hospitals, in the context of medical procedures. *See Morgan v. MacPhail*, 550 Pa. 202, 205 (1997).

Informed consent has not been extended to any type of therapeutic treatment involving an ingestible therapeutic drug, which the court defined as "an ongoing treatment upon examination

by the treating physician, where any change of condition can be diagnosed and controlled.” *Boyer v. Smith*, 345 Pa. Super. 66, 71, 497 A.2d 646, 648 (1985). The Superior Court ruled that the informed consent doctrine is premised upon the legal theory that the performance of a medical procedure without a patient's informed consent constitutes a technical assault or battery and that merely prescribing an oral medication does not involve a touching so not battery can occur and no informed consent is needed. *Id.* at 649. The same principles clearly apply to administration of infant formula to a newborn.

Further, an informed consent claim is only applicable to a physician and not the hospital and/or other health care entities. *See* 40 P.S. § 1303.504; *see also Kelly v. Methodist Hosp.*, 664 A.2d 148 (Pa. Super. 1995) (holding that generally only the physician who performs the operation on the patient has the duty of obtaining his consent for the procedure). The Pennsylvania Supreme Court has held that informed consent involves the relationship between a physician and the patient and that the failure to obtain proper informed consent is deemed a battery, and the institution plays no role in the communications involved in obtaining the same. *See Valles v. Albert Einstein Medical Center*, 805 A.2d 1232 (2002). In *Valles*, the Court decisively ruled that:

We find that a battery which results from a lack of informed consent is not the type of action that occurs within the scope of employment. In our view, a medical facility cannot maintain control over this aspect of the physician-patient relationship. Our lower courts have recognized that the duty to obtain informed consent belongs solely to the physician. (Citations omitted). Informed consent flows from the discussions each patient has with his physician, based on the facts and circumstances each case presents. We decline to interject an element of a hospital's control into this highly individualized and dynamic relationship. We agree with the lower court that to do so would be both improvident and unworkable. Thus, we hold that as a matter of law, a medical facility lacks the control over the manner in which the physician performs his duty to obtain informed consent so as to render the facility vicariously liable.

Id., 805 A.2d at 1239 (emphasis added). The *Valles* case remains the prevailing law in Pennsylvania. Pennsylvania courts have repeatedly applied this doctrine, recognizing and

acknowledging that “[i]n a claim alleging lack of informed consent, it is the conduct of the unauthorized procedure that constitutes the tort.” *Isaac v. Jameson Mem. Hosp.*, 932 A.2d 924, 929 (Pa. Super. 2007) (citing *Moure v. Raeuchle*, 604 A.2d 1003, 1008 (Pa. Super. 1992)). Further, “[g]iven the unique nature of the doctrine and its origins as a technical battery, hospitals cannot be held vicariously liable for a physician’s failure to obtain informed consent because ‘a medical facility cannot maintain control over this aspect of the physician-patient relationship.’” *Isaac*, 932 A.2d at 930. As such, it is clear that the instant cause of action cannot be sustained against Moving Defendants as a matter of law.

B. DEMURRER TO COUNT VII: CORPORATE LIABILITY OF HEALTH CARE PROVIDER

1. Moving Defendants Cannot be Held Liable for Corporate Negligence Regarding a Food Product Which is Permitted for its Intended Use Pursuant to Federal Law

In *Thompson v. Nason Hospital*, 591 A.2d 703, 708 (Pa. 1991), the Pennsylvania Supreme Court recognized the doctrine of corporate liability, holding that a hospital may be found directly liable for negligence if it fails to meet *any* of the following four duties: (1) a duty to use reasonable care in the maintenance of safe and adequate facilities and equipment; (2) a duty to select and retain only competent physicians; (3) a duty to oversee all persons who practice medicine within its walls as to patient care; and (4) a duty to formulate, adopt and enforce adequate rules and policies to ensure quality care for patients.

Plaintiffs’ corporate liability claim fails based on the same rationale as the claim for failure to warn. Both claims are based on the alleged failure to provide warnings to patients related to the use of cow’s milk-based infant formula. As noted above, infant formula is regulated by the FDA, and there is no legal restriction on the use of cow’s milk-based products for feeding of premature infants. Indeed, the Infant Formula Act expressly acknowledges that it is permissible to provide

cow's-milk based products to low birth weight infants. Further, as discussed above, Plaintiffs cannot demonstrate that cow's milk-based formula is a dangerous product. Thus, there is no legal basis to contend that Moving Defendants can be held liable pursuant to a theory of corporate liability for failing to preclude the use of cow's milk-based products in the feeding of premature infants in the hospital.

Additionally, Courts considering the application of the duties set forth in *Thompson* have insisted on more than a simple finding of a negligent act by someone for whom the hospital is purportedly responsible. *Edwards v. Brandywine Hospital*, 652 A.2d 1382 (Pa. Super. 1995). In considering whether the plaintiff could sustain corporate negligence claims based on these allegations, the court analyzed the Thompson decision and delineated the standards required to sustain such a claim:

The *Thompson* theory of corporate liability **will not be triggered every time something goes wrong in a hospital which harms a patient . . .** To establish corporate negligence, a plaintiff must show more than an act of negligence by an individual for whom the hospital is responsible. Rather, Thompson requires a plaintiff to show that the hospital itself is breaching a duty and is somehow substandard...*Thompson* contemplates a kind of 'systemic negligence'...

Id. at 1386-87 (citations omitted and emphasis added). Thus, corporate liability requires "more than individual acts of negligence." *Id.* As noted by the court in *Edwards*, this reading of the Court's opinion in *Thompson* is the only way to logically construe its holding, as hospitals are already held vicariously liable for the negligent acts of their employees and ostensible agents, while "Thompson requires a plaintiff to show that the **hospital itself** is breaching a duty and is somehow substandard." *Id.* at 1387; *see also MacDonald v. Chestnut Hill Hosp.*, 2005 Phila. Ct. Com. Pl. LEXIS 273, 18 (Pa. C.P. 2005) (granting nonsuit to the hospital defendant where "[t]here was no evidence that protocols were routinely ignored to the detriment of patients or that the kind of systematic negligence on the part of CHH required by the *Edwards* decision was present.")

Thus, a hospital may not be held liable via corporate negligence simply based on the alleged negligence of an individual health care provider. Accordingly, even if Plaintiffs could establish that the use of cow's milk-based infant formula was a breach of the standard of care by unidentified health care providers based on the specific circumstances of the Plaintiff-minor's case herein, which has not been pleaded by Plaintiffs considering the paucity of the allegations in the Complaint, such evidence cannot support a finding of corporate liability.

For the reasons stated above, Count VII of Plaintiffs' Complaint should be dismissed with prejudice.

2. Plaintiffs Are Precluded From Pursuing Corporate Negligence Claims as to The Trustees of the University of Pennsylvania

As noted *infra*, the Pennsylvania Supreme Court set forth certain nondelegable duties of hospitals, which if violated may support a finding of corporate negligence. The *Thompson* holding has been extended to HMO's and nursing home facilities, where it was determined that such entities performed similar functions as hospitals. See *Shannon v. Health America Pennsylvania, Inc.*, 718 A.2d 828 (Pa. Super. 1998); *Scampono v. Highland Park Care Center, LLC*, 57 A.3d 582 (Pa. 2012). However, courts have routinely refused to extend the *Thompson* holding past such institutions to cover other entities, such as medical clinics and physician practice groups. See *Sutherland v. Monongahela Valley Hospital*, 856 A.2d 55, 62 (Pa. Super. 2004); *Dowhouer v. Judson*, 45 Pa. D. & C.4th 172, 180 (Pa.Com.Pl. 2000); *Brewer v. Geisinger Clinic, Inc.*, 45 Pa. D. & C.4th 215, 223 (Pa.Com.Pl. 2000); *Dibble v. Penn State Geisinger Clinic, Inc.*, 42 Pa. D. & C.4th 225 (Pa.Com.Pl. 1999); *Davis v. Gish*, 5 Pa. D. & C.5th 154, 159 (Pa.Com.Pl. 2007).

There is no legal basis for holding that the purported corporate parent of a hospital can be held liable under a theory of corporate negligence. The Trustees of the University of Pennsylvania is not a hospital and cannot be held liable under a theory of corporate liability, regardless of its

relationship with Pennsylvania Hospital. Moreover, as Pennsylvania Courts have consistently held, corporate negligence duties are “non-delegable,” i.e., only one entity can be held liable for a breach of these duties. The *Scampone* Court cautioned that the trial court should ensure that “multiple entities are not exposed to liability for breach of the same non-delegable duties.” 57 A.2d at 606-07. Thus, even if a corporate negligence claim were permissible as to Pennsylvania Hospital, which is denied for the reasons stated above, The Trustees of the University of Pennsylvania, which is not a hospital, cannot also be exposed to liability for an alleged breach of the same, non-delegable duties arising out of the same factual allegations. Accordingly, even accepting as true all well pled facts in Plaintiffs’ Complaint, the corporate negligence claims as to the non-hospital Defendant, the Trustees of the University of Pennsylvania, are legally insufficient and must therefore be dismissed.

C. MOTION TO STRIKE PLAINTIFFS’ COMPLAINT FOR INSUFFICIENT SPECIFICITY AS TO THE FACTS AND ALLEGED INJURIES

Pursuant to Pa.R.C.P. 1028(a)(3), a party may file preliminary objections in the nature of a motion to strike for insufficient specificity in a pleading. A plaintiff’s Complaint is required to provide a defendant with notice of what the plaintiff’s claims are and the grounds upon which they rest, and the complaint must also formulate the issues by summarizing the facts essential to support the claims. *Alpha Tau Omega Fraternity v. The University of Pennsylvania*, 464 A.2d 1349, 1352 (Pa. Super. 1983) (*citations omitted*). Pennsylvania Rule of Civil Procedure 1019(a) provides that “the material facts on which a cause of action or defense is based shall be stated in a concise and summary form.” Pa.R.C.P. 1019(a). As the Superior Court has noted,

Rule 1019(a) requires fact pleading. The purpose of 1019(a) is to require the pleader to disclose the material facts sufficient to enable the adverse party to prepare his case. **A complaint therefore must do more than give the defendant fair notice of what the plaintiff’s claim is and the grounds upon which it rests. It should formulate the issues by fully summarizing the material facts. Material facts**

are ultimate facts, i.e., those facts essential to support the claim. Evidence from which such facts may be inferred not only need not but should not be alleged. Allegations will withstand challenge under 1019(a) if (1) they contain averments of all of the facts a plaintiff will eventually have to prove in order to recover, and (2) they are sufficiently specific so as to enable defendant to prepare his defense.

Baker v. Rangos, 324 A.2d 498, 505-506 (Pa. Super. 1974) (citations and internal quotations omitted)(emphasis added).

Further, it is well established that, with regard to the description of injuries sustained by a plaintiff, the Complaint must be stated with sufficient particularity to put the defendant on notice of evidence that may be produced at trial. *Kelly v. Martino*, 99 A.2d 901 (Pa. 1953). **A plaintiff's Complaint must set forth the extent, nature, location and duration of the injuries suffered, and injuries that are permanent should be stated specifically.** *Miller v. Perrige*, 71 Pa. D. & C.2d 476, 479–80 (Pa. Com. Pl. 1975). *See, also, Kopan v. Hawk*, 14 Pa. D. & C.2d 713, 714 (Pa. Com. Pl. 1958) (“A catchall averment of “other injuries” is nothing more than a generalized averment under which any injuries whatever could be proved at the trial. Defendant would have no knowledge in advance of the trial of what they are.”)

Plaintiffs' Amended Complaint is woefully deficient with regard to the specificity of the allegations of the relevant facts and injuries at issue in this case. Plaintiffs' description of the material facts relating to the minor's care and treatment, diagnosis and injuries is limited to four paragraphs, which are utterly insufficient to enable Defendants to prepare their defenses. *See* Exhibit “B,” ¶¶ 11-14. Plaintiffs aver that the minor was born prematurely, the gestational age and birth weight. Plaintiffs' allegation that “upon information and belief,” the minor was fed Similac and/or Enfamil shortly after his birth (*Id.* at ¶ 12) does not comply with the fact-pleading requirements of Rule 1019(a), since such allegations do not provide Moving Defendants with appropriate notice of the facts as to whether the minor actually ingested cow's milk-based

products. Further, Plaintiffs have failed to identify which of the numerous products sold by Abbott and Mead Johnson under the Similac and Enfamil brand names were ingested by the minor. Plaintiffs' Amended Complaint further fails to provide a description of the material facts as to the period of time in which such products were ingested, when the minor was allegedly diagnosed with NEC, what specific treatment was provided for that condition, and for how long.

The Amended Complaint further fails to state the specific nature of the injuries and "long-term health effects" that are alleged to have resulted from the diagnosis of NEC. Plaintiffs' damages claim is not stated with particularity, is amorphous, vague, and open-ended. Pursuant to Pennsylvania pleading requirements, Moving Defendants should not be compelled to defend a claim for which the statement of injury is unspecified and subject to change.

In short, Plaintiffs' Amended Complaint is inconsistent with the requirements of the Pennsylvania Rules of Civil Procedure as to the necessary specificity for the description of the facts and alleged injuries sustained. The facts in the Complaint are pleaded almost entirely "on information and belief." These omissions are fatal defects in Plaintiffs' Amended Complaint. Therefore, Plaintiffs' Amended Complaint should be stricken in its entirety.

D. MOTION TO STRIKE PLAINTIFFS' CLAIMS FOR PUNITIVE DAMAGES

As in the other infant formula cases, In the *Ad Damnum* clauses of Counts VI and VII of the Amended Complaint, Plaintiffs make baseless accusations that Moving Defendants engaged in oppressive, reckless, malicious and/or fraudulent conduct that allegedly justify an award of punitive damages. However, the Amended Complaint contains no specific allegations of conduct that would permit recovery of punitive damages as to Moving Defendants. Rather, Plaintiffs merely allege that "upon information and belief" M.E. may have been given a cow's milk-based infant formula following birth, absent any context to indicate that such an action was inappropriate

based on the specific issues involved in M.E.'s medical care and condition following birth. For example, the Amended Complaint gives no indication of whether Plaintiff-parent refused or was unable to provide breast milk and provides no information as to discussions between her and any health care providers regarding the purported use of cow's milk-based products.

Plaintiffs' allegations of oppressive, malicious and similar conduct must be rejected as mere boilerplate. As discussed above, the FDA specifically approves the use of infant formula in care of low birth weight infants, with no restriction as to the use of cow's milk-based products for such infants. Indeed, the fact that Plaintiffs have filed numerous lawsuits against at least four hospitals in Philadelphia based on identical claims belies the contention that Moving Defendants engaged in outrageous or malicious conduct in allegedly feeding the Plaintiff-minor with cow's milk-based infant formula. Absent specific factual allegations to justify the claim that the use of infant formula in M.E.'s case was extreme and outrageous, there is no basis for an award of punitive damages in this case. Merely contending that punitive damages should be awarded with no supporting factual justification requires dismissal of this claim.

Since the purpose of punitive damages is not compensation of a plaintiff but punishment of the defendant and deterrence, punitive damages can be awarded only for conduct involving some element of outrage. *Hutchinson v. Luddy*, 582 Pa. 114, 870 A.2d 766 (2005). For that reason, Pennsylvania Supreme Court decisions establish that "punitive damages are an 'extreme remedy' available in only the most exceptional matters." *Wagner v. Onofrey*, 2006 Pa. Dist. & Cnty. Dec. LEXIS 333, *11 (Pa. Com. Pl. 2006) (citing *Phillips v. Cricket Lighters*, 584 Pa. 179, 188, 883 A.2d 439, 445 (2005)). "In fact, punitive damages are specifically designed to heap an additional punishment on a defendant who is found to have acted in a fashion which is particularly egregious." *Wagner* at *12.

Punitive damages may not be awarded for misconduct that constitutes ordinary negligence such as inadvertence, mistake and errors of judgment. *Martin v. Johns-Manville Corp.*, 494 A.2d 1088, 1097 (Pa. 1985); *McDaniel v. Merck, Sharp & Dohme*, 533 A.2d 436, 437 (Pa. Super. 1987). An award of punitive damages must be supported by evidence of conduct more serious than the mere commission of the underlying tort. *Allstate Ins. Co. v. A.M. Pugh Assoc., Inc.*, 604 F. Supp. 85, 99 (M.D. Pa. 1984).

Specifically, with regard to punitive damages in the context of claims against health care providers, the Medical Care and Reduction of Error (MCARE) Act permits punitive damages only to be awarded as follows:

- (a) Award. -- Punitive damages may be awarded for conduct that is the result of the health care provider's willful or wanton conduct or reckless indifference to the rights of others. In assessing punitive damages, the trier of fact can properly consider the character of the health care provider's act, the nature and extent of the harm to the patient that the health care provider caused or intended to cause and the wealth of the health care provider.
- (b) Gross Negligence. -- A showing of gross negligence is insufficient to support an award of punitive damages.

41 P.S. §1303.505.

The Supreme Court has made clear that when assessing the propriety of the imposition of punitive damages, "the state of mind of the actor is vital. The act or failure to act, must be intentional, reckless or malicious." *Hutchinson, supra* at 770. An appreciation of the risk is a necessary element of the mental state required for the imposition of punitive damages. *Id.* at 772. Thus, "a punitive damages claim must be supported by evidence sufficient to establish that (1) a defendant had a subjective appreciation of the risk of harm to which the plaintiff was exposed and that (2) he acted, or failed to act, as the case may be, in conscious disregard of that risk." *Id.*

Since professional negligence actions involve allegations that health care professionals deviated from the governing standard of care, punitive damages are generally not recoverable in malpractice actions unless the medical provider's deviation from the applicable standard of care is so egregious as to evince a conscious or reckless disregard of a patent risk of harm to the patient. *Wagner, supra*.

Where the facts as averred show nothing more than negligence, a lapse in judgment, or mere inadvertence, courts in Pennsylvania have dismissed pleas and claims for punitive damages, often at the pleadings stage of litigation and even if the complaint alleged severe injuries or death. *See, e.g., Brownawell v. Bryan*, 40 Pa. D. & C.3d 604, 606 (Pa. Com. Pl. 1985) (dismissing punitive damages claim where a plaintiff alleged that a physician negligently performed a spinal fusion surgery that left the plaintiff with severe neurological defects, and noting that “**the mere pleading of outrageous conduct** does not, of course, satisfy the requirement stating facts which, if proven, would form a basis for a jury concluding that the conduct was such that an award of punitive damages was warranted.”) (emphasis added); *Wagner, supra* at *11 (contentions that physician failed to prescribe antibiotics, order certain tests or request an infectious disease consult constituted “nothing more than ordinary negligence and are insufficient to support an award of punitive damages.”); *McCardle v. Aldinger*, 5 Pa. D. & C.4th 421, 428 (Pa. Com. Pl. 1996) (sustaining preliminary objections and dismissing claim for punitive damages where the plaintiff alleged negligence in the prenatal care of her child that led to the child was stillborn and holding that “[i]t is not the outcome of the alleged negligence that is of consideration, but rather the alleged conduct of defendants that is at issue.”); *Flurer v. Pocono Medical Ctr.*, 15 Pa. D. & C.4th 645, 670 (Pa. Com. Pl. 1992) (sustaining preliminary objections and finding that plaintiffs were not “capable of pleading the requisite behavior” for an award of punitive damages where a hospital allegedly failed

to properly utilize a fetal monitor on a pregnant woman who was involved in a serious car accident and thereafter delivered a stillborn child).

Conversely, punitive damages have been reserved for those situations that are truly egregious and utterly outrageous, and typically involve aggravating or other factors that evince a particularly reckless mind or evil motive. *See, e.g., Medvez v. Choi*, 569 F.2d 1221, 1227-30 (3rd Cir. 1987) (anesthesiologist who abandoned patient on operating room table and left room for a lunch break without securing a suitable replacement could be liable for punitive damages to patient who suffered irreversible paralysis from anesthesia complication that developed during his absence); *Hoffman v. Memorial Osteopathic Hospital*, 492 A.2d 1382, 386-87 (Pa. Super. 1985) (evidence that emergency room physician allowed Guillain-Barre Syndrome patient suffering from neurological paralysis to remain crying and immobile on floor for two hours as physician repeatedly stepped over patient was sufficient to support punitive damages claim); *Guernsey v. County Living Personal Care Home, Inc.*, 2006 U.S. Dist. LEXIS 31450, 2006 WL 1412765 (M.D. Pa. 2006) (punitive damages recoverable from nursing home officials who allowed resident to have access to room of 86-year old Alzheimer's patient where he repeatedly raped her, since nursing home was aware of resident's prior criminal convictions for sex registration as a sexual offender under Megan's Law, and his prior instances of grabbing and kissing staff); *Lawrence v. Kunkle*, 75 D. & C. 4th 370 (Pa. Com. Pl. 2005) (patient could maintain punitive damages claim against physician who refused to perform emergency surgery because patient did not have medical insurance even though physician knew that patient would likely suffer permanent neurologic and functional deficits if surgery was delayed).

All of the cases in the paragraph above set forth examples of egregious conduct, completely inapposite to the facts of the instant case. The facts underlying Plaintiffs' bare assertions of

reckless, outrageous or similar behavior do not even remotely meet the requisite standard under Pennsylvania law that would permit an award of punitive damages. Even assuming the allegations in the Complaint were true for the purposes of this argument only, the outcome in this case was not the result of any intentional wrongdoing or deliberate misconduct on the part of Moving Defendants or any medical provider at Pennsylvania Hospital, nor does the Complaint contain any such allegations.

Additionally, pursuant to § 505(c) of the MCARE Act, punitive damages are specifically restricted in claims involving vicarious liability:

(c) Vicarious liability. -- Punitive damages shall not be awarded against a healthcare provider who is only vicariously liable for the actions of its agent that caused the injury unless it can be shown by a preponderance of the evidence that the party knew of and allowed the conduct of its agent that resulted in an award of punitive damages.

40 P.S. §1303.505(c). Plaintiffs allege in this action that unidentified “staff” fed M.E. Similac and/or Enfamil at Pennsylvania Hospital shortly after his birth and failed to warn Plaintiff-parent of the alleged risks of such products. See Exhibit “B,” ¶ 12. Even if such actions were claimed to be egregious or malicious such that punitive damages were permissible, which is denied for the reasons stated above, Plaintiffs must allege facts to establish that Moving Defendants had actual knowledge of the alleged wrongful conduct and nevertheless allowed it. *See Zazzera v. Roche*, 54 D. & C. 4th 225, 238 (Pa. Com. Pl. 2001); *Dean Witter Reynolds, Inc. v. Genteel*, 499 A.2d 637 (Pa. Super. 1985). In this matter, Plaintiffs have failed to plead any facts to suggest that Moving Defendants were aware of any alleged misconduct by any individual alleged to be an agent and allowed such conduct to continue.

For all these reasons, Plaintiffs’ demand for punitive damages must be stricken with prejudice as to Moving Defendants, along with all allegations of reckless and similar conduct.

E. MOTION TO DISMISS PLAINTIFF-PARENT'S CLAIMS

1. Plaintiff-Parent has Failed to State a Cause of Action

Plaintiff-parent seeks to recover damages in her own right and as the parent and natural guardian of M.E. Plaintiffs' Amended Complaint includes allegations in each count asserted as to Moving Defendants in which it is averred that Plaintiff-parent "suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly altered by the Injured Infant's injuries." *See* Exhibit "B," ¶¶ 142, 155 and 163. However, no specific cause of action is asserted as to any damages sought by Plaintiff-parent in her own right, who is not alleged in the Amended Complaint to have suffered any physical injuries as a result of the alleged negligent conduct of Moving Defendants. For this reason, Plaintiff-parent's claim should be dismissed.

2. Plaintiffs are Required to Plead Separate Claims Pursuant to Pa.R.C.P. 1020

Further, even if Plaintiff-parent had properly articulated a cause of action in the Amended Complaint to allow her to recover damages in her own right, the Amended Complaint should be stricken pursuant to Pa.R.C.P. 1020(b), which provides as follows:

If persons join as plaintiffs under Rules 2228, 2229(a) or (e), the complaint shall state the cause of action, any special damage, and the demand for relief of each plaintiff in a separate count, preceded by a heading naming the parties to the causes of action therein set forth.

Accordingly, it is improper for Plaintiffs to plead in a single count claims on behalf of both the Plaintiff-minor and the Plaintiff-parent, as was done in the Amended Complaint filed herein. Claims on behalf of each of the Plaintiffs must be set forth in separate counts of the Amended Complaint, specifically identifying the cause of action asserted and relief sought in each count.

3. Plaintiff-Parent's Claim Is Precluded Pursuant to the Statute of Limitations

Although the statute of limitations for claims asserted on behalf of minors are tolled until the age of majority, Plaintiff-parent's claims were not similarly tolled and were required to have been brought within two years of the alleged injury. *See Hathi v. Krewstown Park Apts*, 561 A.2d 1261 (Pa. Super. 1989); 42 Pa.C.S. § 5524. Plaintiffs allege that M.E. was born on September 28, 2007, was fed the Defendant manufacturers' products shortly after his birth, and developed NEC shortly thereafter. *See* Exhibit "B," ¶¶ 11-13. Thus, since the Amended Complaint herein was filed on March 24, 2022, Plaintiff-parent's claims herein are clearly time-barred based on the applicable statute of limitations.

In an attempt to circumvent the statute of limitations issues for the Plaintiff-parent, Plaintiffs go to great lengths in their Amended Complaint to essentially assert that Plaintiff-parent's claims are somehow preserved by way of the discovery rule. *See*, Exhibit "B" ¶¶ 24 – 39. More specifically, Plaintiffs have attempted to invoke the Pennsylvania "discovery rule" by arguing that the applicable statute of limitations did not commence until some later date that has not even been plead, due to alleged concealment and misrepresentations. *See* Exhibit "B" at ¶24 - 39.

The discovery rule is a recognized exception to the general rule that a statute of limitations begins to run from the date that a negligent act occurs. The discovery rule provides that where the existence of the injury is not known to the complaining party and such knowledge cannot reasonably be ascertained within the prescribed period, the period of limitation does not begin to run until discovery of the injury is reasonably possible. *Hayward v. Medical Center of Beaver County*, 608 A.2d 1040, 1043 (Pa. 1992). However, in accordance with the discovery rule, a plaintiff need not know the precise medical cause of the injury for the statute of limitations to begin

running; she need only to have known that an injury occurred. *Groover v. Riddle Memorial Hospital*, 357 Pa. Super. 420, 516 A.2d 53 (1986).

Any contention by Plaintiffs that the statute of limitations must be tolled until such time that a plaintiff first suspected that there had been medical negligence with regard to her infant's treatment must similarly be rejected. It is well established in Pennsylvania that a plaintiff need not know the precise extent of injuries before the statutory period begins to run. *Levenson v. Souser*, 384 Pa. Super. 132, 557 A.2d 1081, 1090 (1989). Further, it is well settled law that, in accordance with the discovery rule, a plaintiff need not know that she has a cause of action or suspects there has been negligence before the statute of limitations commences. *Colonna v. Rice*, 664 A.2d 979, 981 (Pa. Super. 1995); *Bigansky v. Thomas Jefferson Univ. Hosp.*, 658 A.2d 423, 427, 431 n.5 (Pa. Super. 1995); *Brooks v. Sagovia*, 636 A.2d 1201, 1204 (Pa. Super. 1994); *E.J.M. v. Archdiocese of Phila.*, 622 A.2d 1388, 1394 (Pa. Super. 1993); *DeMartino v. Albert Einstein Med. Center*, 460 A.2d 295, 298-299 (Pa. Super. 1983). Indeed, it has been expressly held that “[k]nowledge of the negligence is not part of the discovery rule.” *DeMartino, supra*, 460 A.2d at 299. A plaintiff need only know that there was an injury and who caused that injury, a plaintiff need not know the full extent of the injury or even suspect negligence. *Nicolaou v. Martin*, 195 A.3d 880, 892-93 (Pa. 2018); *Gleason v. Borough of Moosic*, 15 A.3d 479, 484 (Pa. 2011); *Wilson v. El-Daief*, 964 A.2d 354, 364 (Pa. 2009).

Based upon the facts plead by Plaintiffs, M.E. is alleged to have developed NEC shortly after his birth. See Exhibit “B” ¶¶11 – 14. Accordingly, Plaintiff-parent knew of an injury in 2007, making any claim in her own right clearly time barred, regardless of whether she knew the extent of any claimed injury and/or when she suspected that the injury was caused by negligence.

The statute of limitations for Plaintiff-parent had clearly expired by the time this action was commenced on March 24, 2022.

**MOTION TO STRIKE PLAINTIFFS' COMPLAINT FOR FAILURE TO
COMPLY WITH Pa.R.C.P. 1024**

Pennsylvania Rule of Civil Procedure 1024(a) requires verification of every pleading containing a factual averment based upon the signer's personal knowledge or information and belief. Rule 1024(c) requires that the verification be made by one or more of the parties filing the pleading. In this case, Plaintiffs' Amended Complaint is unverified in violation of Rule 1024. *See* Exhibit "B." Accordingly, the Amended Complaint should be stricken for lack of an appropriate verification.

V, REQUESTED RELIEF

For the foregoing reasons, Defendants The Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital and The Trustees of the University of Pennsylvania d/b/a Penn Medicine respectfully request that this Honorable Court sustain their Preliminary Objections and enter the attached Order.

BURNS WHITE LLC

BY: _____


JAMES A. YOUNG, ESQ.


RICHARD S. MARGULIES, ESQ.

Attorneys for Defendants,

The Pennsylvania Hospital of the University of
Pennsylvania Health System d/b/a Pennsylvania
Hospital and The Trustees of the University of
Pennsylvania d/b/a Penn Medicine

CERTIFICATE OF SERVICE

I, Richard S. Margulies, Esquire, do hereby certify that on this day I caused a true and correct copy of the foregoing Preliminary Objections of Defendants The Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital and The Trustees of the University of Pennsylvania d/b/a Penn Medicine to Plaintiffs' Amended Complaint, to be served via the electronic filing system to all counsel of record.

BY: 
RICHARD S. MARGULIES, ESQ.

Dated: September 27, 2023

BURNS WHITE LLC

By: James A. Young, Esq.

Samantha L. Conway, Esq.

Attorney ID Nos. 00213/87491

1880 John F. Kennedy Boulevard, 10th Floor
Philadelphia, PA 19103

215-587-1625/1653

jayoung@burnswwhite.com

slconway@burnswwhite.com

Attorneys for All Defendants

Hospital of the University of Pennsylvania;

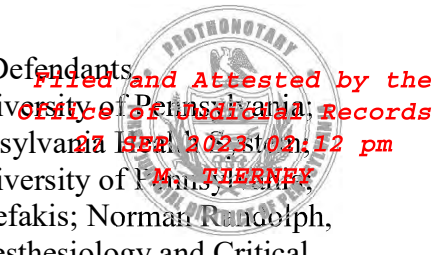
University of Pennsylvania Health System;

Trustees of the University of Pennsylvania;

Dr. Christian A. Refakis; Norman Randolph,

MD; and Penn Anesthesiology and Critical

Care HUP



KIAWANNA CHILDS BENNETT AND
JEMAIN BENNETT, H/W

Plaintiffs,

v.

HOSPITAL OF THE UNIVERSITY OF
PENNSYLVANIA, et al.

Defendants.

COURT OF COMMON PLEAS
PHILADELPHIA COUNTY, PA

CIVIL ACTION

DECEMBER TERM, 2021

NO. 01766

NOTICE OF PRESENTATION

To: Thomas F. Sacchetta, Esquire
Bruce H. MacKnight, Jr., Esquire
Sacchetta & Baldino
308 East Second Street
Media, PA 19063

Please take notice that Defendants' Motion to Compel will be presented on

_____, at 9:00 a.m., in Courtroom _____, City Hall, Philadelphia, Pennsylvania.

BURNS WHITE LLC

Samantha L. Conway

BY:

JAMES A. YOUNG, ESQ.

SAMANTHA L. CONWAY, ESQ.

Attorneys for All Defendants,

Hospital of the University of Pennsylvania,

University of Pennsylvania Health System,

Trustees of the University of Pennsylvania,

Dr. Christian A. Refakis, Norman Randolph,

MD, and Penn Anesthesiology and Critical

Care HUP

Date: September 27, 2023

Certification Due Date: 10/04/2023

Response Date: 10/11/2023

Case ID: 220302566

Control No.: 24096364

KIAWANNA CHILDS BENNETT AND
JEMAINA BENNETT, H/W

Plaintiffs,

v.

HOSPITAL OF THE UNIVERSITY OF
PENNSYLVANIA, et al.

Defendants.

COURT OF COMMON PLEAS
PHILADELPHIA COUNTY, PA

CIVIL ACTION

DECEMBER TERM, 2021
NO. 01766

ORDER

AND NOW, this day of , 2023, upon consideration of Defendants, Hospital of the University of Pennsylvania, University of Pennsylvania Health System, Trustees of the University of Pennsylvania, Dr. Christian A. Refakis, Norman Randolph, MD, and Penn Anesthesiology and Critical Care HUP's, Motion to Compel the depositions of Plaintiffs, Kiawanna Childs Bennett and Jemaine Bennett, and any Response thereto, it is hereby **ORDERED** that said Motion is **GRANTED**.

IT IS FURTHER ORDERED that Plaintiffs Kiawanna Childs Bennett and Jemaine Bennett shall appear for their depositions on October 12, 2023 at 10:00 a.m. at Burns White LLC, 1880 JFK Blvd., 10th Floor, Philadelphia, PA 19103. Failure to comply with this Order shall result in sanctions upon further application to the Court.

BY THE COURT:

J.

Discovery deadline: November 6, 2023

Certification Due Date: 10/04/2023
Response Date: 10/11/2023
Case ID: 220302566
Control No.: 24096364

BURNS WHITE LLC
By: James A. Young, Esq.
Samantha L. Conway, Esq.
Attorney ID Nos. 00213/87491
1880 John F. Kennedy Boulevard, 10th Floor
Philadelphia, PA 19103
215-587-1625/1653
jayoung@burnswwhite.com
slconway@burnswwhite.com

Attorneys for All Defendants,
Hospital of the University of Pennsylvania;
University of Pennsylvania Health System;
Trustees of the University of Pennsylvania;
Dr. Christian A. Refakis; Norman Randolph,
MD; and Penn Anesthesiology and Critical
Care HUP

KIAWANNA CHILDS BENNETT AND
JEMAIN BENNETT, H/W

Plaintiffs,

v.

HOSPITAL OF THE UNIVERSITY OF
PENNSYLVANIA, et al.

Defendants.

COURT OF COMMON PLEAS
PHILADELPHIA COUNTY, PA

CIVIL ACTION

DECEMBER TERM, 2021
NO. 01766

**DEFENDANTS, HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA,
UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM, TRUSTEES OF THE
UNIVERSITY OF PENNSYLVANIA, DR. CHRISTIAN A. REFAKIS, NORMAN
RANDOLPH, MD, AND PENN ANESTHESIOLOGY AND CRITICAL CARE HUP'S,
MOTION TO COMPEL THE DEPOSITIONS OF PLAINTIFFS**

Defendants, Hospital of the University of Pennsylvania, University of Pennsylvania Health System, Trustees of the University of Pennsylvania, Dr. Christian A. Refakis, Norman Randolph, MD, and Penn Anesthesiology and Critical Care HUP, by and through their counsel, Burns White LLC, hereby move to compel the depositions of Plaintiffs, Kiawanna Childs Bennett and Jemaine Bennett, and in support thereof aver as follows:

1. Plaintiffs initiated this medical malpractice action by filing a Complaint on December 27, 2021.

2. On July 20, 2023, Defendants sent Notices of Depositions for Plaintiffs scheduling their depositions to take place on August 1, 2023. *See* a copy of the correspondence and notices attached as Exhibit “A.”

3. On July 26, 2023, Plaintiffs’ depositions were cancelled by Plaintiffs’ counsel’s office. *See* copy of email attached as Exhibit “B.”

4. On September 12, 2023, defense counsel contacted Plaintiffs’ counsel requesting dates for Plaintiffs’ depositions. *See* copy of email attached as Exhibit “C.”

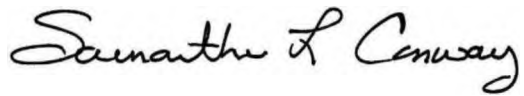
5. On September 21, 2023, defense counsel again contacted Plaintiffs’ counsel and offered dates of availability for Plaintiffs’ depositions to take place. *See* copy of email attached as Exhibit “D.”

6. Plaintiffs’ counsel has not yet complied with our requests.

7. Defendants have exhausted all reasonable steps to conduct said depositions without resorting to the filing of this instant motion.

WHEREFORE, Defendants respectfully request that this Honorable Court order Plaintiffs, Kiawanna Childs Bennett and Jemaine Bennett, to appear for depositions in accordance with the proposed Order.

BURNS WHITE LLC

BY: 
JAMES A. YOUNG, ESQ.
SAMANTHA L. CONWAY, ESQ.
Attorneys for All Defendants,
Hospital of the University of Pennsylvania,
University of Pennsylvania Health System,
Trustees of the University of Pennsylvania,
Dr. Christian A. Refakis, Norman Randolph,
MD, and Penn Anesthesiology and Critical
Care HUP

BURNS WHITE LLC

By: James A. Young, Esq.

Samantha L. Conway, Esq.

Attorney ID Nos. 00213/87491

1880 John F. Kennedy Boulevard, 10th Floor
Philadelphia, PA 19103

215-587-1625/1653

jayoung@burnswwhite.com

slconway@burnswwhite.com

Attorneys for All Defendants,

Hospital of the University of Pennsylvania;

University of Pennsylvania Health System;

Trustees of the University of Pennsylvania;

Dr. Christian A. Refakis; Norman Randolph,

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Care HUP

KIAWANNA CHILDS BENNETT AND
JEMAIN BENNETT, H/W

Plaintiffs,

v.

HOSPITAL OF THE UNIVERSITY OF
PENNSYLVANIA, et al.

Defendants.

COURT OF COMMON PLEAS
PHILADELPHIA COUNTY, PA

CIVIL ACTION

DECEMBER TERM, 2021

NO. 01766

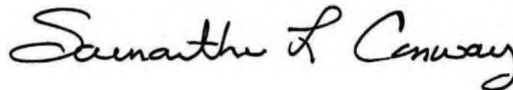
ATTORNEY CERTIFICATE OF GOOD FAITH

The undersigned counsel for movant hereby certifies and attests that:

a) defense counsel has had the contacts described above with opposing counsel regarding the discovery matter contained in the foregoing discovery motion in an effort to resolve the specific discovery dispute at issue and, further, that despite all counsel's good faith attempts to resolve the dispute, counsel have been unable to do so.

Description: Defense counsel has had multiple contacts with Plaintiffs' counsel.

CERTIFIED TO THE COURT BY:



SAMANTHA L. CONWAY, ESQUIRE

Attorney for Defendants

Dated: September 27, 2023

Certification Due Date: 10/04/2023

Response Date: 10/11/2023

Case ID: 220302666

Control No.: 24096364

CERTIFICATE OF SERVICE

Samantha L. Conway, Esquire, hereby certifies that a copy of the foregoing Defendants' Motion to Compel the Depositions of Plaintiffs, was served on this date via electronic filing upon counsel listed below:

Thomas F. Sacchetta, Esquire
Bruce H. MacKnight, Jr., Esquire
Sacchetta & Baldino
308 East Second Street
Media, PA 19063



SAMANTHA L. CONWAY, ESQUIRE

Dated: September 27, 2023

EXHIBIT A

Burns White

ATTORNEYS AT LAW

A Limited Liability Company

Deborah S. Baird | (215) 587-1658 | dsbaird@burnswhite.com

July 20, 2023

VIA EMAIL ONLY

tom@sbattorney.com

bruce@sbattorney.com

Thomas F. Sacchetta, Esquire
Bruce H. MacKnight, Jr., Esquire
Sacchetta & Baldino
308 East Second Street
Media, PA 19063

**RE: Kiawanna Childs Bennett, et al. v. HUP, et al.
CCP, Philadelphia County, December Term, 2021, No. 01766
Our File Number: 14949-276260**

Dear Tom and Bruce,

I am following up from the earlier emails directed to both of you requesting the Plaintiffs' depositions in the above referenced matter. Since I haven't heard from you and the discovery deadline is drawing near, I am forwarding the enclosed Notices of Videotape Deposition. If the dates on the Notices are not agreeable to you, please let me know and we can work together to schedule these depositions at a mutually convenient time. At this juncture, we will proceed with scheduling the Court Reporter for the dates noticed.

Thank you for your consideration and feel free to contact me to discuss this matter at any time.

Very truly yours,

/s/ Deborah S. Baird

Deborah S. Baird

DSB/bcr

Enclosures

cc: James A. Young, Esquire
Samantha L. Conway, Esquire (w/o encls)

BURNS WHITE LLC
By: James A. Young, Esq.
Samantha L. Conway, Esq.
Attorney ID Nos. 00213/87491
1880 John F. Kennedy Boulevard, 10th Floor
Philadelphia, PA 19103
215-587-1625/1653
jayoung@burnswhite.com
slconway@burnswhite.com

Attorneys for All Defendants,
Hospital of the University of Pennsylvania;
University of Pennsylvania Health System;
Trustees of the University of Pennsylvania;
Dr. Christian A. Refakis; Norman Randolph,
MD; and Penn Anesthesiology and Critical
Care HUP

KIAWANNA CHILDS BENNETT AND
JEMAIN BENNETT, H/W

Plaintiffs,

v.

HOSPITAL OF THE UNIVERSITY OF
PENNSYLVANIA, et al.

Defendants.

COURT OF COMMON PLEAS
PHILADELPHIA COUNTY, PA

CIVIL ACTION

DECEMBER TERM, 2021
NO. 01766

**NOTICE OF VIDEOTAPED DEPOSITION OF
PLAINTIFF, KIAWANNA CHILDS BENNETT**

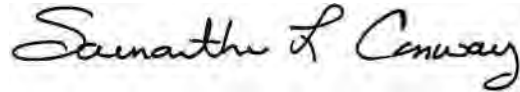
TO: Thomas F. Sacchetta, Esquire
Bruce H. MacKnight, Jr., Esquire
Sacchetta & Baldino
308 East Second Street
Media, PA 19063

PLEASE TAKE NOTICE that in accordance with the Rules of Civil Procedure, the videotaped and stenographically recorded deposition of **Plaintiff, Kiawanna Childs Bennett** will be taken before a person authorized by the laws of the State of Pennsylvania to administer oaths on **Tuesday, August 1, 2023 at 10:00 a.m. at Burns White, LLC, 1880 J.F. Kennedy Blvd., 10th Floor, Philadelphia, PA 19103**, with respect to all matters relevant to the subject matter involved in this action.

Certification Due Date: 10/04/2023
Response Date: 10/11/2023
Case ID: 220302566
Control No.: 24086264

The oral examination will continue from day-to-day until completed. You are invited to appear and take part in the examination.

BURNS WHITE LLC

A handwritten signature in black ink that reads "Samantha L. Conway". The signature is written in a cursive, flowing style.

BY: _____

JAMES A. YOUNG, ESQUIRE
SAMANTHA L. CONWAY, ESQUIRE
Attorneys for All Defendants,
Hospital of the University of Pennsylvania;
University of Pennsylvania Health System; Trustees
of the University of Pennsylvania; Dr. Christian A.
Refakis; Norman Randolph, MD; and Penn
Anesthesiology and Critical Care HUP

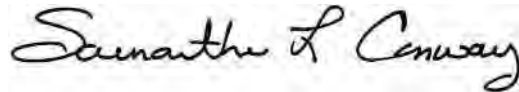
Dated: July 20, 2023

CERTIFICATE OF SERVICE

I, Samantha L. Conway, Esquire, attorney for All Defendants do hereby certify I caused a true and correct copy of the foregoing Notice of Videotaped Deposition to be served upon the following persons listed below via email:

Thomas F. Sacchetta, Esquire
Sacchetta & Baldino
308 East Second Street
Media, PA 19063

BURNS WHITE LLC

A handwritten signature in black ink that reads "Samantha L. Conway". The signature is written in a cursive, flowing style.

BY: _____
Samantha L. Conway, Esquire
Attorney for All Defendants

Dated: July 20, 2023

BURNS WHITE LLC
By: James A. Young, Esq.
Samantha L. Conway, Esq.
Attorney ID Nos. 00213/87491
1880 John F. Kennedy Boulevard, 10th Floor
Philadelphia, PA 19103
215-587-1625/1653
jayoung@burnswhite.com
slconway@burnswhite.com

Attorneys for All Defendants,
Hospital of the University of Pennsylvania;
University of Pennsylvania Health System;
Trustees of the University of Pennsylvania;
Dr. Christian A. Refakis; Norman Randolph,
MD; and Penn Anesthesiology and Critical
Care HUP

KIAWANNA CHILDS BENNETT AND
JEMAIN BENNETT, H/W

Plaintiffs,

v.

HOSPITAL OF THE UNIVERSITY OF
PENNSYLVANIA, et al.

Defendants.

COURT OF COMMON PLEAS
PHILADELPHIA COUNTY, PA

CIVIL ACTION

DECEMBER TERM, 2021
NO. 01766

**NOTICE OF VIDEOTAPED DEPOSITION OF
PLAINTIFF, KIAWANNA CHILDS BENNETT**

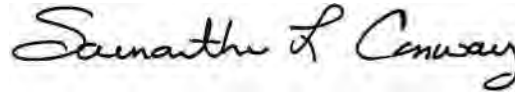
TO: Thomas F. Sacchetta, Esquire
Bruce H. MacKnight, Jr., Esquire
Sacchetta & Baldino
308 East Second Street
Media, PA 19063

PLEASE TAKE NOTICE that in accordance with the Rules of Civil Procedure, the videotaped and stenographically recorded deposition of **Plaintiff, Jemaine Bennett** will be taken before a person authorized by the laws of the State of Pennsylvania to administer oaths on **Tuesday, August 1, 2023 at 2:00 p.m. at Burns White, LLC, 1880 J.F. Kennedy Blvd., 10th Floor, Philadelphia, PA 19103**, with respect to all matters relevant to the subject matter involved in this action.

Certification Due Date: 10/04/2023
Response Date: 10/11/2023
Case ID: 220302566
Control No.: 24096264

The oral examination will continue from day-to-day until completed. You are invited to appear and take part in the examination.

BURNS WHITE LLC

A handwritten signature in black ink that reads "Samantha L. Conway". The signature is written in a cursive, flowing style.

BY: _____

JAMES A. YOUNG, ESQUIRE
SAMANTHA L. CONWAY, ESQUIRE
Attorneys for All Defendants,
Hospital of the University of Pennsylvania;
University of Pennsylvania Health System; Trustees
of the University of Pennsylvania; Dr. Christian A.
Refakis; Norman Randolph, MD; and Penn
Anesthesiology and Critical Care HUP

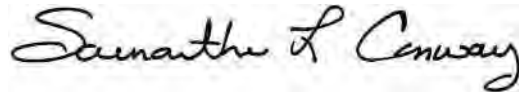
Dated: July 20, 2023

CERTIFICATE OF SERVICE

I, Samantha L. Conway, Esquire, attorney for All Defendants do hereby certify I caused a true and correct copy of the foregoing Notice of Videotaped Deposition to be served upon the following persons listed below via email:

Thomas F. Sacchetta, Esquire
Sacchetta & Baldino
308 East Second Street
Media, PA 19063

BURNS WHITE LLC

A handwritten signature in black ink that reads "Samantha L. Conway". The signature is written in a cursive, flowing style.

BY: _____
Samantha L. Conway, Esquire
Attorney for All Defendants

Dated: July 20, 2023

EXHIBIT B

Lattino, April

Subject: FW: Bennett v. Hospital of the University of Pennsylvania, et al.

From: Jill Newmiller [<mailto:jill@sbattorney.com>]

Sent: Wednesday, July 26, 2023 11:31 AM

To: Reibstein, Betty C. <bcreibstein@burnswhite.com>; Conway, Samantha L. <slconway@burnswhite.com>; Young, James A. <jayoung@burnswhite.com>; Baird, Deborah S. <dsbaird@burnswhite.com>

Cc: Thomas Sacchetta <Tom@sbattorney.com>; Bruce MacKnight <Bruce@sbattorney.com>; Nikki S. LaPorte <Nikki@sbattorney.com>

Subject: RE: Bennett v. Hospital of the University of Pennsylvania, et al.

Good Morning Betty,

I am in receipt of the unilateral NOVD scheduled for August 1, 2023. Unfortunately, our office is not available on that date.

Further, It is our firms' policy not to review/propose deposition dates until all discovery has been exchanged amongst counsel. Conducting a quick search in our database reveals we are still waiting on defendants' answers to roggs & RPD. Please provide a status as to when our office can expect response. Upon receipt, I will be happy to review/propose dates for depositions of defendants and plaintiff to be deposed upon on the same date.

I look forward to working with you in coordinating all calendars,

****PLEASE NOTE, IT IS IMPERATIVE THAT I AM CC'D ON ALL DEPOSITION SCHEDULING EMAILS TO ENSURE NOTHING GOES AMISS.**

Jill Newmiller
Scheduling Coordinator/Paralegal to:
Thomas F. Sacchetta, Esquire
Gerald B. Baldino, Jr., Esquire

From: Reibstein, Betty C. <bcreibstein@burnswhite.com>

Sent: Thursday, July 20, 2023 1:22 PM

To: Thomas Sacchetta <Tom@sbattorney.com>; Bruce MacKnight <Bruce@sbattorney.com>

Cc: Young, James A. <jayoung@burnswhite.com>; Conway, Samantha L. <slconway@burnswhite.com>; Baird, Deborah S. <dsbaird@burnswhite.com>

Subject: Bennett v. Hospital of the University of Pennsylvania, et al.

Good afternoon,

Please see attached letter and notices of deposition being sent on behalf of Deborah S. Baird, Esquire, with regard to the above-captioned matter.

Thank you.

Betty Reibstein

Certification Due Date: 10/04/2023
Response Date: 10/11/2023
Case ID: 220302666
Control No.: 24096364

Betty C. Reibstein
Legal Assistant



1880 John F. Kennedy Boulevard, 10th Floor · Philadelphia, PA 19103
215-587-1631 (O) · 215-587-1699 (F)
bcreibstein@burnswhite.com · burnswhite.com



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EXHIBIT C

Lattino, April

From: Conway, Samantha L.
Sent: Tuesday, September 12, 2023 3:21 PM
To: Nikki S. LaPorte
Cc: Baird, Deborah S.; Lattino, April; Jill Newmiller
Subject: FW: Bennett v. Hospital of the University of Pennsylvania, et al.

Hi Nikki - It is my understanding that you want to set up depositions in this matter. Please provide us with dates for the Plaintiffs (Mr. and Mrs. Bennett) depositions which my partner Deb Baird requested back in mid- July.

April and I will reach out to Dr. Randolph and Dr. Refakis for dates for their depositions. Dr. Refakis is not local - he is not in Boston – Can his deposition be done via zoom? I will likely go to Boston but be with him for his deposition.

Thank, Sam

Samantha L. Conway, Esq.
Member

1880 John F. Kennedy Boulevard, 10th Floor · Philadelphia, PA 19103
215-587-1653 (O) · 610-745-1992 (M) · 215-587-1699 (F)
slconway@burnswwhite.com · burnswwhite.com

From: Jill Newmiller [mailto:jill@sbattorney.com]
Sent: Wednesday, July 26, 2023 11:31 AM
To: Reibstein, Betty C. <bcreibstein@burnswwhite.com>; Conway, Samantha L. <slconway@burnswwhite.com>; Young, James A. <jayoung@burnswwhite.com>; Baird, Deborah S. <dsbaird@burnswwhite.com>
Cc: Thomas Sacchetta <Tom@sbattorney.com>; Bruce MacKnight <Bruce@sbattorney.com>; Nikki S. LaPorte <Nikki@sbattorney.com>
Subject: RE: Bennett v. Hospital of the University of Pennsylvania, et al.

Good Morning Betty,

I am in receipt of the unilateral NOVD scheduled for August 1, 2023. Unfortunately, our office is not available on that date.

Further, It is our firms' policy not to review/propose deposition dates until all discovery has been exchanged amongst counsel. Conducting a quick search in our database reveals we are still waiting on defendants' answers to roggs & RPD. Please provide a status as to when our office can expect response. Upon receipt, I will be happy to review/propose dates for depositions of defendants and plaintiff to be deposed upon on the same date.

I look forward to working with you in coordinating all calendars,

****PLEASE NOTE, IT IS IMPERATIVE THAT I AM CC'D ON ALL DEPOSITION SCHEDULING EMAILS TO ENSURE NOTHING GOES AMISS.**

Jill Newmiller
Scheduling Coordinator/Paralegal to:

Certification Due Date: 10/04/2023
Response Date: 10/11/2023
Case ID: 220302666
Control No.: 24096364

Thomas F. Sacchetta, Esquire
Gerald B. Baldino, Jr., Esquire

From: Reibstein, Betty C. <bcreibstein@burnswhite.com>

Sent: Thursday, July 20, 2023 1:22 PM

To: Thomas Sacchetta <Tom@sbattorney.com>; Bruce MacKnight <Bruce@sbattorney.com>

Cc: Young, James A. <jayoung@burnswhite.com>; Conway, Samantha L. <slconway@burnswhite.com>; Baird, Deborah S. <dsbaird@burnswhite.com>

Subject: Bennett v. Hospital of the University of Pennsylvania, et al.

Good afternoon,

Please see attached letter and notices of deposition being sent on behalf of Deborah S. Baird, Esquire, with regard to the above-captioned matter.

Thank you.

Betty Reibstein

Betty C. Reibstein
Legal Assistant



1880 John F. Kennedy Boulevard, 10th Floor · Philadelphia, PA 19103
215-587-1631 (O) · 215-587-1699 (F)
bcreibstein@burnswhite.com · burnswhite.com



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Certification Due Date: 10/04/2023
Response Date: 10/11/2023
Case ID: 220302666
Control No.: 24086364

EXHIBIT D

Lattino, April

From: Baird, Deborah S.
Sent: Thursday, September 21, 2023 1:29 PM
To: Conway, Samantha L.; Nikki S. LaPorte
Cc: Lattino, April; Jill Newmiller; Pentz, Evan S.
Subject: RE: Bennett v. Hospital of the University of Pennsylvania, et al.

Hi again Nikki,
Unfortunately, I am no longer free on October 4th to take the Plaintiff's depositions. Please let me know if either of the other 2 dates will work. If not, I will serve up some other options.
Thanks!
Deb

From: Baird, Deborah S. <dsbaird@burnswhite.com>
Sent: Thursday, September 21, 2023 7:08 AM
To: Conway, Samantha L. <slconway@burnswhite.com>; Nikki S. LaPorte <Nikki@sbattorney.com>
Cc: Lattino, April <alattino@burnswhite.com>; Jill Newmiller <jill@sbattorney.com>; Pentz, Evan S. <espentz@burnswhite.com>
Subject: RE: Bennett v. Hospital of the University of Pennsylvania, et al.

Hi Nikki,
We would like to schedule Plaintiffs' depositions on either Wednesday October 4th, Thursday October 12th or Wednesday October 18th. Please let us know which of the above dates works best for you.
Thanks!
Deb

Deborah S. Baird, Esq.
Of Counsel



1880 John F. Kennedy Boulevard, 10th Floor · Philadelphia, PA 19103
215-587-1658 (O) · 215-587-1699 (F)
dsbaird@burnswhite.com · burnswhite.com



From: Conway, Samantha L. <slconway@burnswhite.com>
Sent: Tuesday, September 12, 2023 3:21 PM

Certification Due Date: 10/04/2023
Response Date: 10/11/2023
Case ID: 220302666
Control No.: 24096364

To: Nikki S. LaPorte <Nikki@sbattorney.com>

Cc: Baird, Deborah S. <dsbaird@burnswwhite.com>; Lattino, April <alattino@burnswwhite.com>; Jill Newmiller <jill@sbattorney.com>

Subject: FW: Bennett v. Hospital of the University of Pennsylvania, et al.

Hi Nikki - It is my understanding that you want to set up depositions in this matter. Please provide us with dates for the Plaintiffs (Mr. and Mrs. Bennett) depositions which my partner Deb Baird requested back in mid- July.

April and I will reach out to Dr. Randolph and Dr. Refakis for dates for their depositions. Dr. Refakis is not local - he is not in Boston – Can his deposition be done via zoom? I will likely go to Boston but be with him for his deposition.

Thank, Sam

Samantha L. Conway, Esq.
Member

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215-587-1653 (O) · 610-745-1992 (M) · 215-587-1699 (F)
slconway@burnswwhite.com · burnswwhite.com

From: Jill Newmiller [<mailto:jill@sbattorney.com>]

Sent: Wednesday, July 26, 2023 11:31 AM

To: Reibstein, Betty C. <bcreibstein@burnswwhite.com>; Conway, Samantha L. <slconway@burnswwhite.com>; Young, James A. <jayoung@burnswwhite.com>; Baird, Deborah S. <dsbaird@burnswwhite.com>

Cc: Thomas Sacchetta <Tom@sbattorney.com>; Bruce MacKnight <Bruce@sbattorney.com>; Nikki S. LaPorte <Nikki@sbattorney.com>

Subject: RE: Bennett v. Hospital of the University of Pennsylvania, et al.

Good Morning Betty,

I am in receipt of the unilateral NOVD scheduled for August 1, 2023. Unfortunately, our office is not available on that date.

Further, It is our firms' policy not to review/propose deposition dates until all discovery has been exchanged amongst counsel. Conducting a quick search in our database reveals we are still waiting on defendants' answers to roggs & RPD. Please provide a status as to when our office can expect response. Upon receipt, I will be happy to review/propose dates for depositions of defendants and plaintiff to be deposed upon on the same date.

I look forward to working with you in coordinating all calendars,

****PLEASE NOTE, IT IS IMPERATIVE THAT I AM CC'D ON ALL DEPOSITION SCHEDULING EMAILS TO ENSURE NOTHING GOES AMISS.**

Jill Newmiller
Scheduling Coordinator/Paralegal to:
Thomas F. Sacchetta, Esquire
Gerald B. Baldino, Jr., Esquire

From: Reibstein, Betty C. <bcreibstein@burnswwhite.com>

Sent: Thursday, July 20, 2023 1:22 PM

To: Thomas Sacchetta <Tom@sbattorney.com>; Bruce MacKnight <Bruce@sbattorney.com>

Cc: Young, James A. <jayoung@burnswwhite.com>; Conway, Samantha L. <slconway@burnswwhite.com>; Baird, Deborah S. <dsbaird@burnswwhite.com>

Subject: Bennett v. Hospital of the University of Pennsylvania, et al.

Good afternoon,

Please see attached letter and notices of deposition being sent on behalf of Deborah S. Baird, Esquire, with regard to the above-captioned matter.

Thank you.

Betty Reibstein

Betty C. Reibstein
Legal Assistant



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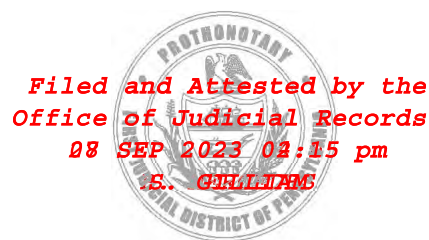
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Elizabeth.crawford@klinespecter.com

Jack.oneill@klinespecter.com



ALICE STILLS, on her own behalf and as Parent
and Natural Guardian of M.E., a Minor,

Plaintiff,

v.

MEAD JOHNSON & COMPANY, LLC, MEAD
JOHNSON NUTRITION COMPANY, ABBOTT
LABORATORIES, THE TRUSTEES OF THE
UNIVERSITY OF PENNSYLVANIA d/b/a PENN
MEDICINE, and PENNSYLVANIA HOSPITAL OF THE
UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM
d/b/a PENNSYLVANIA HOSPITAL,

Defendants.

: **IN THE COURT OF COMMON PLEAS**
: **PHILADELPHIA COUNTY**
:
: **CIVIL TRIAL DIVISION**
:
: **MARCH TERM 2022**
: **NO. 2617**

NOTICE TO PLEAD AND DEFEND

NOTICE

You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so the case may proceed without you and a judgment may be entered against you by the court without further notice for any money claimed in the complaint or for any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER

ADVISO

Le han demandado a usted en la corte. Si usted quiere defenderse de estas demandas expuestas en las paginas siguientes, usted tiene veinte (20) dias de plazo al partir de la fecha de la demanda y la notificacion. Hace falta asentar una comparencia escrita o en persona o con un abogado y entregar a la corte en forma escrita sus defensas o sus objeciones a las demandas en contra de su persona. Sea avisado que si usted no se defiende, la corte tomara medidas y puede continuar la demanda en contra suya sin previo aviso o notificacion. Ademas, la corte pueda decidir a favor del demandante y requiere que usted cumpla con todas las provisiones de esta demanda. Usted puede perder dinero o sus propiedades u otros derechos importantes para usted.

LLEVE ESTA DEMANDA A UN ABOGADO INMEDIATAMENTE, SI

AT ONCE. IF YOU DO NOT HAVE A LAWYER, GO TO
OR TELEPHONE THE OFFICE SET FORTH BELOW TO
FIND OUT WHERE YOU CAN GET LEGAL HELP.

Lawyer Referral Service
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1101 Market Street, 11th Floor
Philadelphia, PA 19107
(215) 238-6338

NO TIENE ABOGADO O SI NO TIENE EL DINERO SUFICIENTE DE
PAGAR TAL SERVICIO, VAYA EN PERSONA O LLAME POR
TELEFONO A LA OFICINA CUYA DIRECCION SE ENCUENTRA
ESCRITA ABAJO PARA AVERIGUAR DONDE SE PUEDE
CONSEGUIR ASISTENCIA LEGAL.

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ALICE STILLS, on her own behalf and as Parent
and Natural Guardian of M.E., a Minor,

Plaintiff,

V.

MEAD JOHNSON & COMPANY, LLC, MEAD
JOHNSON NUTRITION COMPANY, ABBOTT
LABORATORIES, THE TRUSTEES OF THE
UNIVERSITY OF PENNSYLVANIA d/b/a PENN
MEDICINE, and PENNSYLVANIA HOSPITAL OF THE
UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM
d/b/a PENNSYLVANIA HOSPITAL,

Defendants.

: **IN THE COURT OF COMMON PLEAS**
 : **PHILADELPHIA COUNTY**
 :
 : **CIVIL TRIAL DIVISION**
 :
 : **MARCH TERM 2022**
 : **NO. 2617**

FIRST AMENDED COMPLAINT

Plaintiff brings this Amended Complaint and Demand for Jury Trial (the “Amended Complaint”) against Mead Johnson & Company, LLC, Mead Johnson Nutrition Company, and Abbott Laboratories (collectively “the Defendant Manufacturers”), and The Trustees of the University of Pennsylvania d/b/a Penn Medicine and Pennsylvania Hospital of the University of

Pennsylvania Health System d/b/a Pennsylvania Hospital (collectively “Penn Medicine” or “Pennsylvania Hospital”), together “Defendants.” Plaintiff alleges the following upon personal knowledge as to Plaintiff’s own acts and experiences and upon information and belief, including investigation conducted by Plaintiff’s attorneys, as to all other matters.

I. INTRODUCTION

1. This action arises out of the injuries suffered by a premature infant (the “Injured Infant”) who was given the Defendant Manufacturers’ cow’s milk-based infant feeding products at Pennsylvania Hospital. Pennsylvania Hospital, managed by Penn Medicine, acquired and supplied the Defendant Manufacturers’ products to the Injured Infant and negligently failed to warn of their unreasonably dangerous properties in a reasonable manner. This caused the Injured Infant to develop necrotizing enterocolitis (“NEC”), a life-altering and potentially deadly disease that largely affects premature babies who are given cow’s milk-based feeding products. As a result, the Injured Infant was seriously injured, resulting in long term health effects and accompanying harm to their parent (“the Plaintiff Parent”).

2. Plaintiff brings these causes of action against Defendants to recover for injuries that are the direct and proximate result of the Injured Infant’s consumption of the Defendant Manufacturers’ unreasonably dangerous cow’s milk-based infant feeding products, which were acquired and supplied without adequate warning to the Injured Infant at Pennsylvania Hospital, owned and operated by Penn Medicine.

II. PARTIES

3. Plaintiff Alice Stills is a natural adult person and a resident of Pennsylvania. Ms. Stills is the parent and natural guardian of M.E., a minor. Ms. Stills’s address is 656 N Conestoga Street, Philadelphia, Pennsylvania 19131.

4. Defendant Mead Johnson Nutrition Company is a corporation, incorporated under the laws of the State of Delaware. Its principal place of business is Illinois. Defendant Mead Johnson & Company, LLC, is a limited liability company, organized under the laws of the State of Delaware. Its citizenship is that of its sole member, Mead Johnson Nutrition Company. Defendants Mead Johnson Nutrition Company and Mead Johnson & Company, LLC, (together, “Mead”) are manufacturers of cow’s milk-based infant feeding products and market many of these products under the “Enfamil” brand name.

5. Defendant Abbott Laboratories (“Abbott”) is a corporation, incorporated under the laws of the State of Illinois. Its principal place of business is in Illinois. Abbott is a manufacturer of cow’s milk-based infant feeding products and markets many of its products under the “Similac” brand name.

6. Defendant The Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital is a non-profit corporation incorporated and registered to do business under the laws of the Commonwealth of Pennsylvania. Its principal place of business is Philadelphia, Pennsylvania. Pennsylvania Hospital is a registered name of The Pennsylvania Hospital of the University of Pennsylvania Health System. The sole member of The Pennsylvania Hospital of the University of Pennsylvania Health System is The Trustees of the University of Pennsylvania.

7. Defendant The Trustees of the University of Pennsylvania d/b/a Penn Medicine is a non-profit corporation registered to do business in the Commonwealth of Pennsylvania. Its principal place of business is Philadelphia, Pennsylvania. Penn Medicine is a registered name of The Trustees of the University of Pennsylvania.

III. JURISDICTION AND VENUE

8. This Court has jurisdiction in this matter pursuant to 42 Pa. C.S.A. § 931. Defendants conduct authorized business in the Commonwealth of Pennsylvania. They have sufficient minimum contacts with and purposefully avail themselves of the markets of this Commonwealth. This suit arises out of Defendants' forum-related activities, such that the Court of Common Pleas of Philadelphia County's exercise of jurisdiction would be consistent with traditional notions of fair play and substantial justice.

9. Venue is proper in the Court of Common Pleas of Philadelphia County pursuant to Rules 1006(b), 1006(c)(1), and 2179(a) of the Pennsylvania Rules of Civil Procedure because Defendants are corporations or similar entities that regularly conduct business in Philadelphia County, which is also the county where Plaintiff's causes of action arose, and the county where the occurrences took place out of which Plaintiff's causes of action arose.

10. This action is not subject to the Compulsory Arbitration Program of the Court of Common Pleas of Philadelphia County because the amount in controversy, excluding interest and costs, is in excess of \$50,000.

IV. FACTUAL ALLEGATIONS

M.E.'s NEC Diagnosis

11. M.E. was born prematurely at Pennsylvania Hospital in Philadelphia, Pennsylvania on September 28, 2007.

12. At birth, M.E.'s gestational age was approximately 28 weeks and he weighed 907 grams. Upon information and belief, M.E. was fed Similac and/or Enfamil cow's milk-based products by staff at Pennsylvania Hospital after his birth.

13. Upon information and belief, M.E. developed NEC after ingesting Defendant Manufacturers' products.

14. M.E.'s diagnosis of NEC occurred during his course of treatment at Defendant Hospital's NICU. M.E. suffered injuries, including but not limited to, a diagnosis of NEC, treatment with antibiotics and surgery, feeding difficulties, neurological injuries, developmental delays, and growth issues and he continues to suffer other long-term health effects.

***Cow's Milk-Based Feeding Products Are Known to Cause
NEC***

15. NEC is a devastating disease that is the most frequent and lethal gastrointestinal disorder affecting preterm infants. NEC develops when harmful bacteria breach the walls of the intestine, causing portions of the intestine to become inflamed and often to die. Once NEC develops, the condition can progress rapidly from mild feeding intolerance to systemic and fatal sepsis. Up to 30 percent of NEC-diagnosed infants die from the disease.

16. Preterm and low-birth-weight infants are especially susceptible to NEC because of their underdeveloped digestive systems. Extensive scientific research, including numerous randomized controlled trials, has confirmed that cow's milk-based feeding products cause NEC in preterm and low-birth-weight infants, which in turn may lead to other medical complications, surgeries, long-term health problems, and death.

Safer, Nutritionally Superior Alternatives to Cow's Milk-Based Products Exist

17. A range of options are available that allow preterm and low-birth-weight infants to be fed exclusively human milk-based nutrition. For example, in addition to the mother's own milk, an established network delivers pasteurized donor breast milk to hospitals nationwide. Moreover, hospitals have access to shelf-stable formula and fortifiers derived from pasteurized breast milk.

18. A diet based exclusively on breast milk and breast milk fortifiers provides all the nutrition necessary to support premature and low-birth-weight infants without the elevated risk of NEC associated with cow's milk-based products.

19. The Defendant Manufacturers' products not only pose a threat to infants' health, but also displace the breast milk they could otherwise receive. This displacement only increases infants' vulnerability to NEC.

20. Breast milk-based nutrition nourishes infants while creating a significantly lower risk of NEC.

21. At the time the Injured Infant was fed the Defendant Manufacturers' products, the science clearly demonstrated to Defendants that these products cause NEC and greatly increase the likelihood that a baby will develop NEC, leading to severe injury and often death.

22. Despite the scientific consensus that the Defendant Manufacturers' cow's milk-based products present a dire threat to the health and development of preterm infants, the Defendant Manufacturers have made no changes to their products or the products' packaging, guidelines, instructions, or warnings. Instead, they have continued to sell their unreasonably dangerous products. In addition, they incentivize hospitals that know the risks to use their products by providing them to the hospital for free or at a significant discount, in order that vulnerable infants and their families will become accustomed to using their products before discharge. And, in fact, the Defendant Manufacturers offer contracts to hospitals—which the hospitals accept—that actually *prevent* the health care providers from offering alternative products—even safer ones—on pain of risking the hospital's advantageous formula pricing strategy.

Ms. Stills Discovers Her Claim

23. Because of the Defendants' concealment and misrepresentations, described more fully herein, Ms. Stills did not know, and had no reason to know or suspect, that M.E.'s NEC could have been caused by the Defendant Manufacturers' products.

***Despite Exercising Diligence, a Reasonable Investigation Did Not Reveal and
Would Not Have Revealed a Factual Basis Earlier
Because Defendants Hid the Cause of NEC from Ms. Stills***

24. Despite exercising reasonable diligence, Ms. Stills was unable to have made the discovery earlier via a reasonable investigation because the Defendants in this litigation concealed the wrongful cause of M.E.'s injuries.

25. Not one person at Penn Medicine mentioned that the Defendant Manufacturers' formula products could have caused M.E.'s injuries. Penn Medicine's response at the time did not give Ms. Stills any reason to suspect any wrongdoing on the part of the Defendants.

26. Ms. Stills is a layperson with no medical background or training that would have given her any reason to doubt the response she received from her Penn Medicine health care providers at the time.

27. Given that Penn Medicine's health care providers were in charge of the care of her newborn infant, Ms. Stills had no reason to doubt their word.

28. Additionally, the risk of necrotizing enterocolitis was not disclosed on the labeling or packaging of *any* of the Defendant Manufacturers' products.

29. What is more, necrotizing enterocolitis is a disease that can occur in children who are *not* fed the Defendant Manufacturers' products, and the Defendant Manufacturers have worked to mislead parents into a false sense of security about the use of those products. Publicly disseminated materials from each Defendant Manufacturer disguise the role their products play in causing the disease—and affirmatively say, even today, that their products are safe and do not cause NEC. In fact, some publicly disseminated materials from the formula manufacturers even suggest that formula may help *reduce* the risk of this terrible and potentially fatal disease.

30. For example, Abbott’s website stays that “[t]he specific cause of NEC is unknown, but it’s most often seen in very low birth weight premature babies,” and that “about 10% of babies who are born prematurely develop NEC.” The website suggests that “new preliminary studies” suggest for the first time that “NEC prevention may . . . be possible” with the use of human milk oligosaccharides to “dramatically curb intestinal inflammation” and reduce the risk of NEC. Abbott states that these human milk oligosaccharides are found in “certain Similac formulas” although they are “not currently available in Similac’s premature infant formulas.”¹ Likewise, the website for Mead Johnson’s products states that necrotizing enterocolitis is “one of the most common and serious intestinal disease[s] among premature babies.” And it deflects responsibility from Mead Johnson’s products: “Necrotizing enterocolitis happens when tissue in the small or large intestine is injured or inflamed.”²

31. Because of the misleading information distributed by the Defendant Manufacturers, as further detailed below, a reasonable person would not suspect that the Defendant Manufacturers’ products could have caused M.E.’s injuries.

32. Ms. Stills also did not know, and had no reason to know or suspect, that Penn Medicine breached its duty of care by distributing the Defendant Manufacturers’ products to him. Not only was Ms. Stills unaware that the Defendant Manufacturers’ products caused M.E.’s injuries, but the Defendant Manufacturers’ distribution agreements with Penn Medicine—which allowed Penn Medicine to secure sweetheart deals for otherwise expensive premature infant formula in exchange for product placement and access to the hospital staff—were also not public or knowable to Ms.

¹ The Role of HMOs in Reducing NEC, <https://www.nutritionnews.abbott/pregnancy-childhood/prenatal-breastfeeding/the-promising-role-of-hmos-in-reducing-risk-of-nec/> (last visited July 28, 2023).

² Special Feeding Concerns for Preemies, <https://www.enfamil.com/articles/special-feeding-concerns-for-preemies/> (last visited July 29, 2023).

Stills, nor could any reasonable investigation outside of litigation have uncovered the terms of those agreements.

Despite Exercising Reasonable Diligence, the Defendants' Fraudulently Concealed the Risks of NEC from Defendant Manufacturers' Products to Divert, Prevent, and Mislead Plaintiff Regarding the Cause of Her Child's NEC Diagnosis

33. In addition to the averments above, the Defendants have acted in concert to fraudulently convey false and misleading information concerning the risk of NEC, and potentially death, caused by Defendant Manufacturers' preterm infant formula products.

34. The Defendants' actions as set forth herein constitute knowing misrepresentation, omission, suppression, and concealment of material facts, made with the intent that Plaintiff would rely upon such concealment, suppression, or omission, in connection with the use of Defendants' preterm infant products.

35. Plaintiff did not know, and could not learn, the truth concerning the uses, risks and benefits of Defendant Manufacturers' preterm infant products due to Defendants' deliberate misrepresentations and concealment, suppression and omission of material facts and important information regarding the risks of NEC, and potentially death, from the products.

36. Moreover, Defendant Hospital further participated in the intentional concealment—on information and belief, it allowed the Defendant Manufacturers' sales representatives into its hospital to provide samples and free products that did not warn of their serious dangers, and to provide “education” to its NICU staff that was incomplete as to the true risks of feeding their patients the Defendant Manufacturers' products.

37. Additionally, Defendant Hospital failed to inform Ms. Stills that the Defendant Manufacturers' products caused Plaintiff's NEC. As noted above, after learning of Plaintiff's NEC diagnosis, Ms. Stills was understandably concerned about the degrading health of her newborn

infant. But even though Defendant Hospital knew of the increased risk of NEC from formula, it did not disclose that the formula provided to M.E. could increase the risk of NEC to preterm infants. Not one person at the NICU mentioned that the Defendant Manufacturers' formula products could have been the cause of Plaintiff's injuries.

38. Defendant Hospital was aware that the Defendant Manufacturers' products caused NEC in premature infants. Defendant Hospital was also aware that the Defendant Manufacturers did not provide warnings on their products. However, Defendant Hospital did not warn Ms. Taylor of the risks of the products. Instead, and notwithstanding the sweetheart deal Defendant Hospital agreed to in exchange for preterm infant formula at little to no cost, Defendant Hospital repeatedly informed Ms. Stills that it would do everything it could possibly do to keep her infant safe. Though this was clearly not true given the known risks of preterm formula for babies like M.E., it was enough for Ms. Stills to trust that Defendant Hospital was providing preterm formula in the best interest of her child.

39. Defendants' affirmative acts of fraud and concealment, as averred herein, diverted, prevented, and/or mislead Plaintiff from discovering the medical cause of her child's NEC diagnosis.

The Defendant Manufacturers' False and Misleading Marketing Regarding Cow's Milk-Based Infant Products

40. Abbott and Mead have aggressively marketed their cow's milk-based products as medically endorsed and nutritionally equivalent alternatives to breast milk, including prior to the Injured Infant's birth.

41. Abbott's and Mead's marketing approach includes targeting the parents of preterm infants while they are still in the hospital with messages that the Defendant Manufacturers' cow's milk formulas and fortifiers are necessary for the growth and development of their vulnerable children.

Often these tactics implicitly discourage mothers from breastfeeding, which reduces the mother's supply of breast milk. None of the Defendant Manufacturers' marketing materials, including their promotional websites, reference the science showing how significantly their products increase the risk of NEC.

42. Undoubtedly aware of the impact of their advertising, the Defendant Manufacturers, along with other formula manufacturers, are willing to spend massive sums to disseminate their message.

43. Recognizing the abuse and dangers of infant formula marketing, in 1981, the World Health Assembly—the decision-making body of the World Health Organization—developed the International Code of Marketing of Breast-milk Substitutes (“the Code”), which required companies to acknowledge the superiority of breast milk, the negative effect on breastfeeding of introducing partial bottle-feeding, and the difficulty of reversing the decision not to breastfeed. The Code also forbade advertising or other forms of promotion of formula to the general public, as well as providing sample products to mothers or members of their families.

44. While Abbott and Mead acknowledge the Code on their websites and claim to support the effort to encourage mothers to breastfeed for as long as possible, this is little more than lip service. Instead, the Defendant Manufacturers' aggressive marketing exploits new parents' darkest fears—that the nutrition they are supplying to their child will not provide the best chance of survival—while wholly failing to warn that their products come with a significantly increased risk of NEC.

45. For example, Abbott's website, on a page titled “Infant Formula Marketing,” states: “We agree with the World Health Organization that breastfeeding provides the best nutrition for babies, and we support its goal to increase breastfeeding. We also recognize that for infants who aren't breastfed—for medical reasons or otherwise—infant formula is the only appropriate, safe

alternative to meet babies' nutritional needs." This statement ignores the existence of donor milk, as well as human milk-based formula.

46. Abbott markets and sells multiple products specifically targeting preterm and low-birthweight infants, including Liquid Protein Fortifier, Similac NeoSure, Similac Human Milk Fortifiers, Similac Special Care 20, Similac Special Care 24, Similac Special Care 24 High Protein, and Similac Special Care 30. In advertising these products, Abbott emphasizes the products' purported ability to assist underdeveloped babies in reaching their growth targets. For example, on the since-edited webpage regarding Similac NeoSure, Abbott noted: "Your premature baby didn't get her full 9 months in the womb, so her body is working hard to catch up. During her first full year, feed her Similac NeoSure, a nutrient-enriched formula for babies who were born prematurely, and help support her development." Yet, no mention was made of the accompanying significantly increased risk of NEC. At some point, the website was edited to remove this statement. However, upon information and belief, the statement remained on the website until at least December 2020.

47. Mead markets and sells multiple products specifically targeting premature infants, including Enfamil NeuroPro EnfaCare Infant Formula, Enfamil Premature Infant Formula 24 Cal High Protein, Enfamil Premature Infant Formula 30 Cal with Iron, Enfamil Premature Infant Formula 24 Cal with Iron, Enfamil Premature Infant Formula 20 Cal with Iron, Enfamil 24 Cal Infant Formula, and Enfamil Human Milk Fortifier (acidified liquid and powder). In advertising these products, Mead emphasizes the purported similarities between its formula and breast milk, while failing to include any information about the nutritional deficits and dangers that accompany formula use. For example, the since-edited webpage for Enfamil Enfacare stated: "Premature babies fed Enfamil® formulas during the first year have achieved catch-up growth similar to that

of full term, breastfed infants” and noted that Enfamil formulas include “expert-recommended levels of DHA and ARA (important fatty acids found naturally in breast milk) to support brain and eye development.”

48. One Enfamil advertisement, introducing a new product line called Enfamil NeuroPro, is entirely focused on favorably comparing Enfamil’s formula to breast milk, without any mention of the product’s extreme risks. Indeed, the terms “human milk” and “breast milk” are used 13 times in the advertisement, including in such statements as “for decades human milk has inspired the advancements in Enfamil formulas and now through extensive global research, we are taking an even closer look at human milk” and “only Enfamil NeuroPro has a fat blend of MFGM and DHA previously found only in breast milk.” The webpage for the product has made similar manipulative claims, stating “Enfamil is backed by decades of breast milk research and multiple clinical studies” and it claims that “to create our best formulas, we collaborated on some of the most extensive breast milk studies to date[.]”

49. Formula manufacturers have long used their relationships with hospitals and the discharge process to encourage parents to substitute formula for breast milk. They offer free or reduced-cost formula to hospitals for use with infants before discharge. And they offer free formula, coupons, and even entire gift baskets to parents before their infants’ discharge from the NICU or hospital.

50. Through this early targeting, the Defendant Manufacturers create brand loyalty under the guise of a “medical blessing,” in hopes that new parents continue to use formula after they leave the hospital, resulting in increased expense for parents, significantly increased risk for babies, and increased profit for the Defendant Manufacturers. The Defendant Manufacturers’ giveaways and gift baskets send confusing signals to mothers who are simultaneously being encouraged to breastfeed by their healthcare professionals, and they have been shown to negatively impact

breastfeeding rates.

51. Further, when the Defendant Manufacturers recognized a shift in the medical community towards an exclusive breast milk-based diet for premature infants, Abbott developed a product called “Similac Human Milk Fortifier,” and Mead developed “Enfamil Human Milk Fortifier.” These names are misleading in that they suggest that the products are derived from breast milk, when, in fact, they are cow’s milk-based products. The packaging appears as:



52. The Defendant Manufacturers have designed powerful misleading marketing campaigns to deceive parents into believing that: (1) cow’s milk-based products are safe, including for preterm infants; (2) cow’s milk-based products are equal, or even superior, substitutes to breast milk; (3) cow’s milk-based products are necessary for proper growth and development of preterm infants; and (4) physicians consider the Defendant Manufacturers’ cow’s milk-based products to be a first

choice. This marketing scheme is employed despite all Defendants knowing of and failing to warn of the extreme risk of NEC and death that cow's milk-based products pose to preterm infants like the Injured Infant.

53. The Defendant Manufacturers have also designed powerful marketing campaigns to both the general public and health care providers at hospitals like Pennsylvania Hospital. The Defendant Manufacturers know that sales made to hospitals are key drivers of brand loyalty, and thus are a key opportunity to drive better downstream business—*i.e.*, retail purchases by parents after they have left the hospital. On information and belief, the Defendant Manufacturers know that the formula products used in a hospital's NICU are related to getting and keeping the overall hospital contracts. And the Defendant Manufacturers know that, just like any celebrity endorsement, when mothers of newborn infants see medical professionals using a certain brand, the mothers are more likely to continue to purchase that same brand after discharge. The Defendant Manufacturers are thus heavily motivated to ensure that NICU departments are using their products.

54. Abbott and Mead Johnson focus their sales teams and training heavily on hospital NICU departments. They train their sales representatives how to increase the number of babies on their formula, and they emphasize the need to be the dominant formula manufacturer in the NICU so they can own that profitable ground and secure a great return on their substantial investment in NICU formula and other products.

55. To leverage hospitals' NICUs and secure babies in the hospital and at retail, the Manufacturer Defendants pull out all the stops to convince hospitals, including Defendant Hospital, to purchase their products. For example: Abbott and Mead Johnson provide samples of their products to hospitals for free.

56. On information and belief, to get the hospitals on board with supplying their formula for premature infants, Abbott and Mead Johnson work with hospitals to secure contracts that have special pricing discounts if a certain level of the formula-fed babies in the hospital receive just that one manufacturer's products; similar to a restaurant being a Coke or Pepsi restaurant. And notwithstanding the increased risk of the Defendant Manufacturers' products for the hospitals' most fragile patients—the preterm infants—the decision makers at these hospitals seek out these types of contracts to better the hospitals' own bottom lines.

57. On information and belief, Abbott and Mead Johnson also seek promises and/or assurances that the full range of health care providers at the hospitals, including the nurse practitioners and other staff who would pull the infant formula off the shelf, are grabbing the respective company's own formula products to give to the preterm infants. The goal of this tactic was to ensure that the Defendant Manufacturers and key people at the hospital would be sending a shared message that the preterm infant formula products were safe and without risk, even though that is not what the science said.

58. Prior to M.E.'s birth, Abbott sent sales representatives to Defendant Hospital. Those sales representatives provided information about Abbott's products to Defendant Hospital's staff via conversations, presentations, and written pamphlets. This information indicated that Abbott's products were safe to give to preterm infants like M.E. Abbott maintains call logs that detail which sales representatives visited the hospitals, which days they visited, and which products they discussed. These sales representatives did not disclose that Abbott's products could cause NEC in preterm infants.

59. Prior to M.E.'s birth, Mead Johnson sent sales representatives to Defendant Hospital. Those sales representatives provided information about Mead Johnson's products to Defendant

Hospital's staff via conversations, presentations, and written pamphlets. This information indicated that Mead Johnson's products were safe to give to preterm infants like M.E. Mead Johnson maintains call logs that detail which sales representatives visited the hospitals, which days they visited, and which products they discussed. These sales representatives did not disclose that Mead Johnson's products could cause NEC in preterm infants.

60. Mead Johnson and Abbott believed and intended that the misrepresentations that its sale representatives shared with Defendant Hospital would be used to make feeding decisions for preterm infants like M.E.

The Defendant Manufacturers' Inadequate Warnings

61. Although Mead promotes an aggressive marketing campaign designed to convince parents that its cow's milk-based products are safe and necessary for the growth of a premature infant, the product is in fact extremely dangerous for premature infants. Enfamil products significantly increase the chances of a premature infant developing potentially fatal NEC.

62. The Enfamil products Mead markets specifically for premature infants are commercially available at retail locations and online. No prescription is necessary.

63. Despite knowing of the risk of NEC, the packaging of Mead's products does not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with Mead's products, or of the magnitude of this increased risk. Mead likewise did not provide instructions or guidance for how to avoid NEC.

64. Mead cites no medical literature or research to guide the use of its products.

65. Despite knowing of the risk of NEC, Mead did not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with its products, or of the magnitude of this increased risk. Mead likewise did not provide instructions or guidance for how to avoid NEC.

66. Mead deceived the public, parents, physicians, other medical professionals, and medical staff into believing that Enfamil products were a safe and necessary alternative, supplement and/or substitute to breast milk.

67. Mead Johnson failed to provide, and continues to fail to provide, a full accounting of the risk of NEC as documented, by underrepresenting and misrepresenting the risk to the public and the medical community.

68. Despite knowing that its products were being fed to premature infants, often without the parents' informed consent, Mead failed to require or recommend that medical professionals inform parents of the significant risk of NEC or to require that parental consent be obtained prior to the products being fed to their babies. Like Mead, Abbott promotes an aggressive marketing campaign designed to make parents believe that its products are safe and necessary for the growth of premature infants, despite the products in fact being extremely dangerous for premature infants. Abbott's products significantly increase the chances of a premature infant getting potentially fatal NEC.

69. The products Abbott markets specifically for premature infants are available at retail locations and online. No prescription is necessary.

70. Despite knowing of the risk of NEC, Abbott did not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with its products, or of the magnitude of this increased risk. Abbott likewise did not provide instructions or guidance for how to avoid NEC.

71. Abbott deceived the public, parents, physicians, other medical professionals, and medical staff into believing that its products were a safe and necessary alternative, supplement and/or substitute to breast milk.

72. Despite knowing of studies documenting an increased risk of NEC from its products, Abbott did not act to make parents or the medical community aware of those risks, and instead took steps to conceal or prevent those risks from becoming public. Despite knowing that its products were being fed to premature infants, often without the parents' informed consent, Abbott failed to require or recommend that medical professionals inform parents of the significant risk of NEC or to require that parental consent be obtained prior to the products being fed to their babies.

Penn Medicine's Failure to Warn

73. On information and belief, Penn Medicine, which operates Pennsylvania Hospital, was aware of the significantly increased risk of NEC and death associated with providing Abbott's and Mead's cow's milk-based products to its premature infant patients. It knew or should have known that feeding these cow's milk-based products can cause NEC in premature infants who otherwise would not have developed this devastating condition. However, instead of warning of the dangers, or supplying breast milk-based feeding products to preterm infants like the Injured Infant, Penn Medicine has continued to source, distribute, and supply the Defendant Manufacturers' products in its hospitals without any adequate warning.

74. To that end, Penn Medicine has participated in studies designed to increase the use of donor milk while, at the same time, reducing formula feeding in neonates. The University of Pennsylvania School of Nursing, an affiliate of Penn Medicine, has conducted extensive research into the risks associated with feeding formula to premature infants. It recently partnered with the National Institute of Nursing Research to publish clinical determinations based on its experience "changing hospital systems and influencing policy," and its findings were unequivocal:

This is what we know about the science of human milk: it reduces the risk of necrotizing enterocolitis, reduces the risk of infection, [and] creates greater enteral feed tolerance and more rapid weaning from intravenous nutrition. . . .

Other Penn Medicine research has similarly concluded that "[h]uman milk decreases the incidence

and severity of . . . necrotizing enterocolitis (NEC).”

75. Penn Medicine also purports to adhere to the tenets of the “Baby Friendly Hospital Initiative,” which seeks to increase rates of breastfeeding initiation, exclusivity, and diet duration. The “Baby Friendly Hospital Initiative” specifically targets a reduction in the rates of NEC in preterm infants by encouraging implementation of exclusive breast milk diets among new mothers. Although Pennsylvania Hospital has maintained its “Baby Friendly” designation for years, it has not eliminated or restricted the use of formula or fortifier for preterm infants in its hospitals.

76. Finally, medical providers and staff at Penn Medicine have acknowledged the risks associated with providing the Defendant Manufacturers’ cow’s milk-based products to premature infant patients instead of breast milk-based nutrition. In an internal newsletter from 2012 touting donor milk programs, Penn Medicine acknowledged the benefits of a human milk-based diet, quoting a staff lactation consultant:

Donor milk is not inexpensive. It costs about \$4.25 per ounce, but the return on investment is huge. “Preemies given mother’s milk get discharged three to four days sooner and also have a six to 10 times lower risk of getting a gastrointestinal complication called necrotizing enterocolitis,” Carpenter said, adding that the infection can cost up to \$250,000 to treat. The average cost to provide a preemie with donor milk: \$125.

77. These statements demonstrate that Penn Medicine knew or should have known of the high increased risk of NEC for premature infants posed by the Defendant Manufacturers’ products.

78. Although Penn Medicine knew or should have known of the serious danger of the Defendant Manufacturers’ products, it has continued to purchase, supply, and distribute these products to preterm infants without providing full and adequate warnings of the attendant risks to parents, healthcare professionals, and other medical staff at its relevant facilities. As a result, the Injured Infant was fed the Defendant Manufacturers’ cow’s milk-based products at Pennsylvania

Hospital, causing their injuries. This occurred even though hospitals across the country, including Pennsylvania Hospital, warn and obtain consent from parents before providing other safer forms of nutrition, such as donor breast milk.

79. Penn Medicine's failure to warn of the risks posed by the Defendant Manufacturers' products is entrenched (and compounded) by the financial benefits it accrues from its relationships with the Defendant Manufacturers. On information and belief, it has received the Defendant Manufacturers' cow's milk-based products for free and/or at a significant discount, and has granted their sales representatives access to its healthcare professionals and medical staff. These sales representatives have provided deceptive information that Penn Medicine reasonably knew or should have known would ultimately reach parents through those staff. This arrangement dovetails with the Defendant Manufacturers' own marketing strategies" and use of salespersons.

Safer Alternative Designs

80. The Defendant Manufacturers' cow's milk-based products made specifically for premature infants are unreasonably unsafe for those infants. The Defendant Manufacturers could have used pasteurized breast milk instead of cow's milk in their products, which would have produced a safer product.

81. Prolacta Bioscience manufactures and sells breast milk-based feeding products, specifically designed for preterm infants, which contain no cow's milk. This alternative design provides all the necessary nutrition for growth and development that cow's milk-based products provide, without the same unreasonably dangerous and deadly effects.

82. On information and belief, Abbott and Mead were aware of the significantly increased risk of NEC and death associated with their cow's milk-based products, and instead of warning of the dangers, or removing them altogether, Abbott and Mead have continued to use cow's milk as the

foundation of their products.

CAUSES OF ACTION
COUNT I: STRICT LIABILITY FOR DESIGN DEFECT
(Against Abbott and Mead)

83. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

84. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to manufacture, sell, and distribute their products in a manner that was not unreasonably dangerous.

85. Abbott and Mead also owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to manufacture, sell, and distribute their products in a manner that was merchantable and reasonably suited for their intended use.

86. Abbott and Mead knew that their products would be used to feed premature infants like the Injured Infant and knew (or reasonably should have known) that use of their cow's milk-based products significantly increased the risk of NEC, serious injury, and death, and that such use was therefore unreasonably dangerous to premature infants, not reasonably suited for the use intended, not merchantable, and had risks that exceeded a reasonable buyer's expectations. Nonetheless, they continued to sell and market their defective products as appropriate for premature infants.

87. The Injured Infant ingested Abbott and/or Mead's unreasonably dangerous cow's milk-based products. The risks of feeding those products to the Injured Infant outweighed the benefits. An ordinary consumer would not expect those products to carry a significant risk of serious injury and death from NEC.

88. Abbott and Mead knew (or reasonably should have known) that breast milk-based nutrition did not carry the same risks of NEC, serious injury, and death that their products do.

89. Abbott's and Mead's products contained cow's milk at the time they left the manufacturing facility.

90. Abbott and Mead did not develop a human-milk based product that was safer for premature infants and did not reformulate their products to reduce the risk of NEC, serious injury, and death, even though doing so was economically and technologically feasible and even though pasteurized breast milk was an available alternative.

91. Abbott's and/or Mead's products were fed to the Injured Infant, which caused and/or increased the risk of their NEC and injuries.

92. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;

- d. For punitive damages in excess of \$50,000 and this Court's arbitral limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT II: STRICT LIABILITY FOR FAILURE TO WARN
(Against Abbott and Mead)**

93. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

94. Abbott and Mead, as the manufacturers and/or sellers of the infant products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide adequate warnings or instructions about the dangers and risks associated with the use of their products with preterm infants, specifically including but not limited to the risk of NEC, serious injury, and death.

95. Abbott's and Mead's duty to warn is part of their general duty to design, manufacture, and sell their infant products in a manner that is reasonably safe for their foreseeable uses. By designing their products with cow's milk-based ingredients, Abbott and Mead undertook a duty to warn of the unreasonable risk of harm posed by those ingredients, specifically including the significantly increased risk of NEC, severe injury, and death. The failure to warn makes the products at issue in this litigation unreasonably dangerous.

96. Specifically, Abbott and Mead breached their duty to warn of the foreseeable risks of the infant products at issue in this litigation because they knew or should have known that their

cow's milk-based premature infant products would be fed to premature infants like the Injured Infant, and that their products might cause the Injured Infant to develop NEC, severe injury, or death, yet they failed to provide adequate warnings of those risks. Among other risks, the Defendant Manufacturers:

- a. Failed to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death for the Injured Infant; and/or
- b. Failed to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or
- c. Inserted warnings and instructions on their products that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC and death; and/or
- d. "Black box"-type warning that their cow's milk-based products are known to significantly increase the risk of NEC and death when compared to breast milk in premature infant; and/or
- e. Failed to disclose well-researched and well-established studies that linked cow's milk-based products to NEC and death in premature infants; and/or
- f. Failed to insert a warning or instruction to healthcare professionals and other medical staff in the hospital that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risks; and/or
- g. Failed to provide a warning in a method reasonably calculated or expected

to reach the parents of newborns, like the Plaintiff Parent; and/or

- h. Failed to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products.

97. Abbott's and Mead's products contained cow's milk at the time they left the manufacturing facility.

98. As a direct and proximate result of the inadequacy of the warnings and the pervasive marketing campaigns suggesting the safety and necessity of the Defendant Manufacturers' products, the Injured Infant were fed cow's milk-based products, which caused and/or increased risk of their developing NEC.

99. The unwarned-of risks are not of a kind that an ordinary consumer would expect. Had physicians and medical staff known of the extreme risk associated with feeding premature infants cow's milk-based formula, they would not have fed the Injured Infant those products. Had the Plaintiff Parent known of the significant risks of feeding the Injured Infant cow's milk-based formula, they would not have allowed such products to be fed to the Injured Infant.

100. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of

enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;

- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitral limit resulting from the Defendants Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT III: NEGLIGENCE
(Against Abbott and Mead)**

101. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

102. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to exercise reasonable care to design, test, manufacture, inspect, and distribute a product free of unreasonable risk of harm to users, when such products are used in their intended manner and for their intended purpose.

103. At all times relevant to this action, the Injured Infant's healthcare professionals and medical

staff used the products at issue in their intended manner and for their intended purpose.

104. Abbott and Mead, directly or indirectly, negligently, and/or defectively made, created, manufactured, designed, assembled, tested, marketed, sold, and/or distributed the cow's milk-based infant products at issue in this litigation and thereby breached their duty to the general public and the Plaintiff Parent.

105. Specifically, although Abbott and Mead knew or reasonably should have known at the time of production that their cow's milk-based infant products significantly increased the risk of NEC, serious injury, and death, they failed to act in a reasonably prudent manner and breached their duty by:

- a. Failing to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death for the Injured Infant; and/or
- b. Failing to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or
- c. Inserting warnings and instructions that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC and death; and/or
- d. Failing to insert a large and prominent "black box"-type warning that their cow's milk-based products are known to significantly increase the risk of NEC and death when compared to breast milk in premature infants; and/or
- e. Failing to provide well-researched and well-established studies that linked cow's milk-based products to NEC and death in premature infants; and/or
- f. Failing to insert a warning or instruction to healthcare professionals and

other medical staff in the hospital that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risks; and/or

- g. Failing to provide a warning in a method reasonably calculated/expected to reach the parents of newborns, like the Plaintiff Parent; and/or
- h. Failing to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products.

106. In addition, although Abbott and Mead knew or reasonably should have known at the time of production that their cow's milk-based products significantly increased the risk of NEC, serious injury, and death, they failed to act in a reasonably prudent manner and breached their duty by failing to perform the necessary process of data collection, detection, assessment, monitoring, prevention, and reporting or disclosure of adverse outcomes in infants who ingest their products.

107. As a direct and proximate result of the Defendant Manufacturers' failure to act in a reasonably prudent manner and their breach of duty, the Injured Infant was fed cow's milk-based products, which caused and/or increased the risk of their developing NEC.

108. Had Abbott and Mead satisfied their duties to the consuming public in general, the Injured Infant would not have been exposed to their unreasonably dangerous cow's milk-based products.

109. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers,

individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendants Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT IV: INTENTIONAL MISREPRESENTATION
(Against Abbott and Mead)**

110. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

111. At all times relevant to this action, the Injured Infant consumed the Defendant Manufacturers' products in their intended manner and for their intended purpose.

112. Abbott and Mead, as the manufacturers and/or sellers of the infant products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide truthful, accurate, fulsome information about the risks and benefits of using their products when used in the intended manner and for the intended purpose.

113. Abbott and Mead breached their duty through misrepresentations made to consumers, physicians, and medical staff in their advertising and promotional materials, as described in previous paragraphs and incorporated herein, each of whom were foreseeable and intended recipients of this information.

114. Specifically, upon information and belief, Abbott and Mead made the following false statements of material fact on an ongoing and repeated basis and prior to the time the Injured Infant was fed their products:

- a. That their cow's milk-based products were safe and beneficial for premature infants when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or
- b. That their cow's milk-based products were necessary to the growth and nutrition of premature infants, when they knew or should have known that their products were not necessary to achieve adequate growth; and/or
- c. That their products have no serious side effects, when they knew or should have known the contrary to be true; and/or
- d. That cow's milk-based products were safe for premature infants; and/or
- e. That cow's milk-based products were necessary for optimum growth; and/or
- f. That cow's milk-based products were similar or equivalent to breast milk;

and/or

- g. That their products were safe and more like breast milk than other infant products and that they had removed the harmful ingredients of cow's milk when, in fact, the cow's milk in their products was still capable of causing NEC, serious injury, and death; and/or
- h. That their products were based on up-to-date science, which made them safe for premature infants; and/or
- i. Omitting the material fact that their products significantly increased the risk of NEC in premature infants.

115. Abbott and Mead had actual knowledge, or, at a minimum, a reckless indifference, to whether the aforementioned misrepresentations were false. The Defendant Manufacturers' misrepresentations were intended to, and in fact did, mislead physicians and medical staff, including the Injured Infant's physicians and medical staff, to provide their infant products to babies, including the Injured Infant.

116. The Plaintiff Parent was not aware that these misrepresentations were false and justifiably relied on them. The Defendant Manufacturers' misrepresentations induced the Plaintiff Parent to allow their children to be fed Abbott's and Mead's infant products, in reliance on all the messaging they received about formula feeding, including, directly or indirectly, the Defendant Manufacturers' messaging. Had Abbott and Mead not committed these intentional misrepresentations, the Injured Infant would not have been exposed to the Defendant Manufacturers' unreasonably dangerous cow's milk-based products.

117. As a direct and proximate result, Abbott's and Mead's products were fed to the Injured Infant, which caused and/or increased risk of their developing NEC and subsequent injuries.

118. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT V: NEGLIGENT MISREPRESENTATIONS
(Against Abbott and Mead)**

119. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

120. At all times relevant to this action, the Injured Infant consumed the products at issue in their intended manner and for their intended purpose.

121. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide truthful, accurate, and complete information about the risks and benefits of using their products when used in the intended manner and for the intended purpose.

122. In the course of their business, Abbott and Mead breached their duty through misrepresentations made to consumers, physicians, and medical staff in their advertising and promotional materials, as described in previous paragraphs and incorporated herein, each of whom were foreseeable recipients of this information.

123. Specifically, upon information and belief, Abbott and Mead made the following false statements of material fact on an ongoing and repeated basis and prior to the time the Injured Infant was fed their products:

- a. That their cow's milk-based products were safe and beneficial for premature infants when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or
- b. That their cow's milk-based products were necessary to the growth and nutrition of premature infants, when they knew or should have known that their products were not necessary to achieve adequate growth; and/or
- c. That their products have no serious side effects, when they knew or should

have known the contrary to be true; and/or

- d. That cow's milk-based products were safe for premature infants; and/or
- e. That cow's milk-based products were necessary for optimum growth; and/or
- f. That cow's milk-based products were similar or equivalent to breast milk; and/or
- g. That their products were safe and more like breast milk than other infant products and that they had removed the harmful ingredients of cow's milk when, in fact, the cow's milk in their products was still capable of causing NEC, serious injury, and death; and/or
- h. That their products were based on up-to-date science, which made them safe for premature infants; and/or
- i. Omitting the material fact that their products significantly increased the risk of NEC in premature infants.

124. Abbott and Mead were negligent or careless in not determining those representations to be false.

125. The Defendant Manufacturers' misrepresentations were intended to and did in fact induce physicians and medical staff, including the Injured Infant's physicians and medical staff, to provide their products to babies, including the Injured Infant.

126. The Defendant Manufacturers' misrepresentations induced, and were intended to induce, the Plaintiff Parent to allow their child to be fed Abbott's and Mead's infant products, in justifiable reliance on all the messaging they received about formula feeding, including, directly or indirectly, the Defendant Manufacturers' messaging. Had Abbott and Mead not committed these negligent misrepresentations, the Injured Infant would not have been exposed to their unreasonably

dangerous cow's milk-based products.

127. As a direct and proximate result, Abbott's and Mead's products were fed to the Injured Infant, which caused and/or increased of their developing NEC and subsequent injuries.

128. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection

with this action; and

g. For such other and further relief as the Court deems proper.

**COUNT VI: FAILURE TO WARN
(Against Penn Medicine and Pennsylvania Hospital)**

129. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

130. Penn Medicine and Pennsylvania Hospital as purchaser, supplier, and/or distributor of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to purchase, supply, and distribute products that were free of unreasonable risk of harm when used in their intended manner and for their intended purpose, and/or to formulate, adopt, and enforce adequate rules and policies for the same.

131. At all times relevant to this action, the Injured Infant used the cow's milk-based products purchased, supplied, and/or distributed by Penn Medicine and Pennsylvania Hospital in their intended manner and for their intended purpose.

132. Penn Medicine and Pennsylvania Hospital employed or contracted with the healthcare professionals and medical staff at Pennsylvania Hospital, managing these individuals during their treatment of the Injured Infant.

133. Penn Medicine and Pennsylvania Hospital negligently, outrageously, and recklessly supplied and distributed the Defendant Manufacturers' milk-based infant feeding products to these healthcare professionals and medical staff for use on premature infants, including the Injured Infant.

134. Moreover, at all relevant times, Penn Medicine and Pennsylvania Hospital knowingly authorized the Defendant Manufacturers' sales representatives to market, advertise, distribute, and/or sell their products at Pennsylvania Hospital. The Defendant Manufacturers' sales

representatives were encouraged to interact with Pennsylvania Hospital's healthcare professionals and medical staff. These interactions provided the Defendant Manufacturers' sales representatives an opportunity to co-opt Pennsylvania Hospital's healthcare professionals and medical staff into assisting with the marketing, distribution, and/or sale of the Defendant Manufacturers' unreasonably dangerous products to consumers, such as the Plaintiff Parent.

135. Penn Medicine and Pennsylvania also knowingly, and intentionally, allowed the Defendant Manufacturers' sales representatives to routinely misrepresent the risks and benefits of Defendants' products to Pennsylvania Hospital's healthcare professionals and medical staff, including the misrepresentation that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

136. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known at the time that they acquired, distributed, and supplied the Defendant Manufacturers' cow's milk-based infant products that these products significantly increased the risk of NEC, serious injury, and death.

137. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, outrageously, and recklessly, and breached its duty by:

- a. Failing to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in those babies; and/or
- b. Failing to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or
- c. Failing to warn or instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice about whether to allow their babies to be fed the Defendant

Manufacturers' products, notwithstanding their substantial risk; and/or

- d. Failing to provide its healthcare professionals and medical staff with the well- researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or
- e. Failing to provide a warning in a method reasonably calculated/expected to reach the parents of newborns; and/or
- f. Failing to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products; and/or
- g. Failing to prevent the Defendant Manufacturers' sales representatives from misrepresenting to Pennsylvania Hospital's healthcare professionals and medical staff that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

138. Reasonable hospitals under the same or similar circumstances would have warned of the above risks, would have instructed their healthcare professionals and medical staff—as well as patients—on the safe use of the Defendant Manufacturers' products, and would have restricted the ability of the Defendant Manufacturers' sales representatives to market the Defendant Manufacturers' unreasonably dangerous products without adequate warning.

139. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that its medical professionals and the parents of premature infants, including the Plaintiff Parent, would not have realized the risks associated with feeding cow's milk-based formula to premature infants.

140. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its

duty to warn its medical providers and patients about the Defendant Manufacturers' unreasonably dangerous products, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

141. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital's failure to warn of the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

142. As a further direct and proximate result of Penn Medicine and Pennsylvania Hospital's failure to warn of the Defendant Manufacturers' unreasonably dangerous products, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against Penn Medicine and Pennsylvania Hospital, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of Penn Medicine's conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational

limit resulting from Penn Medicine and Pennsylvania Hospital's oppressive, outrageous, reckless, and/or malicious conduct, as permitted by law;

- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT VII: CORPORATE LIABILITY OF HEALTH-CARE PROVIDER
(Against Penn Medicine and Pennsylvania Hospital)**

143. Plaintiff incorporates by references each of the preceding paragraphs as if fully set forth herein.

144. At all relevant times, Penn Medicine and Pennsylvania Hospital owed a duty of care to the Injured Infant to ensure their safety and well-being while the Injured Infant was under the care of Pennsylvania Hospital staff. Specifically, Penn Medicine and Pennsylvania Hospital had a duty to the Injured Infant to formulate, adopt, and enforce adequate rules and policies to ensure quality care for the Injured Infant. Further, Penn Medicine and Pennsylvania Hospital owed a duty to the Injured Infant to oversee its healthcare professionals and medical staff that provided patient care to the Injured Infant.

145. Penn Medicine and Pennsylvania Hospital owed a duty to its patients, and the Injured Infant in particular, to formulate, adopt, and enforce adequate rules and policies for the purchase, supply, distribution, and use of products that were free of unreasonable risk of harm when used in their intended manner and for their intended purpose and ensured quality care for the Injured Infant.

146. At all times relevant to this action, the Injured Infant used the cow's milk-based products purchased, supplied, and/or distributed by Penn Medicine and Pennsylvania Hospital in their

intended manner and for their intended purpose.

147. Moreover, at all relevant times, Penn Medicine and Pennsylvania Hospital knowingly authorized the Defendant Manufacturers' sales representatives to market, advertise, distribute, and/or sell their products at Pennsylvania Hospital. The Defendant Manufacturers' sales representatives were encouraged to interact with Pennsylvania Hospital's healthcare professionals and medical staff. These interactions provided the Defendant Manufacturers' sales representatives an opportunity to co-opt Pennsylvania Hospital's healthcare professionals and medical staff into assisting with the marketing, distribution, and/or sale of the Defendant Manufacturers' unreasonably dangerous products.

148. Penn Medicine and Pennsylvania Hospital also knowingly allowed the Defendant Manufacturers' sales representatives to routinely misrepresent the risks and benefits of Defendants' products to Pennsylvania Hospital's healthcare professionals and medical staff, including the misrepresentation that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

149. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known at the time that it formulated, adopted, and enforced its rules for the acquisition, distribution, and supply of the Defendant Manufacturers' cow's milk-based infant products, including the access afforded the Defendant Manufacturer's sales representatives, that these products significantly increased the risk of NEC, serious injury, and death for premature infants.

150. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that its medical professionals and the parents of premature infants, including the Plaintiff Parent, would not have realized the risks associated with feeding cow's milk-based formula to premature infants.

151. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, outrageously,

and recklessly, and breached its duty by:

- a. Failing to formulate, adopt, and enforce adequate rules and policies that would have restricted the use of cow's milk-based products for feeding premature babies; and/or
- b. Failing to formulate, adopt, and enforce adequate rules and policies that warned the Plaintiff Parent that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in premature babies, like the Injured Infant; and/or
- c. Failing to formulate, adopt, and enforce adequate rules and policies that warned its healthcare professionals and medical staff that cow's milk-based products are unsafe and/or contraindicated for premature babies like the Injured Infant; and/or
- d. Failing to formulate, adopt, and enforce adequate rules and policies to instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risk; and/or
- e. Failing to formulate, adopt, and enforce adequate rules and policies to provide its healthcare professionals and medical staff with the well-researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or
- f. Failing to formulate, adopt, and enforce adequate rules and policies to ensure a warning in a method reasonably calculated/expected to reach the

parents of newborns, like the Plaintiff Parent; and/or

- g. Failing to formulate, adopt, and enforce adequate rules and policies to prevent the Defendant Manufacturers' sales representative from misrepresenting to Pennsylvania Hospital's healthcare professionals and medical staff that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants; and/or
- h. Failing to establish a donor milk program that was sufficient to meet the needs of the premature babies, like the Injured Infant.

152. A reasonable hospital under the same or similar circumstances would have formulated, adopted, and enforced adequate policies, and rules to restrict the feeding of cow's milk-based products to premature babies, including developing an adequate donor milk program, instructing its healthcare professionals and medical staff on the safe use of Defendants Manufacturers' cow's milk-based products, and restricting the marketing of the Defendant Manufacturers' unreasonably dangerous products to its healthcare professionals, medical staff, and parents of premature infants under its care.

153. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its duty to formulate, adopt, and enforce adequate rules and policies to ensure the quality care of its patients, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

154. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital failure to formulate and enforce adequate policies and rules related to the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the

Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

155. As a further direct and proximate result of Penn Medicine and Pennsylvania Hospital negligent, reckless, and outrageous conduct the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

156. In the alternative, Penn Medicine and Pennsylvania Hospital owed a duty to its patients, and the Injured Infant in particular, to oversee the practicing healthcare professionals and medical staff that provided the products at issue to infants under Pennsylvania Hospital's care, including the Injured Infant.

157. Penn Medicine and Pennsylvania Hospital employed or contracted with the healthcare professionals and medical staff at Pennsylvania Hospital and was responsible for overseeing those individuals during their treatment of the Injured Infant.

158. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, recklessly, and outrageously breached its duty by:

- a. Failing to oversee its healthcare professionals and medical staff on their use of cow's milk-based products for feeding premature babies; and/or
- b. Failing to warn or instruct its healthcare professionals and medical staff that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in those babies; and/or
- c. Failing to warn or instruct its healthcare professionals and medical staff that cow's milk-based products are unsafe and/or contraindicated for premature babies like the Injured Infant; and/or

- d. Failing to oversee its healthcare professionals and medical staff to restrict their feeding of cow's milk-based products to premature babies; and/or
- e. Failing to warn or instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risk; and/or
- f. Failing to provide its healthcare professionals and medical staff with the well- researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or
- g. Failing to provide its healthcare professionals and medical staff with warnings about the dangers of the Defendants' Manufacturers products in a method reasonably calculated/expected to reach the parents of newborns; and/or
- h. Failing to provide statistical evidence to its healthcare professionals and medical staff showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products; and/or
- i. Failing to oversee its healthcare professionals and medical staff to ensure that the Defendant Manufacturers' sales representatives' misrepresentations that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants had not influenced the use and/or misuse of the Defendant Manufacturers' products.

159. A reasonable hospital under the same or similar circumstances would have warned of the

above risks, would have instructed its healthcare professionals and medical staff on the safe use of the Defendant Manufacturers' products, and would have restricted the ability of the Defendant Manufacturers' sales representatives to market the Defendant Manufacturers' unreasonably dangerous products without adequate warning.

160. A reasonable hospital under the same or similar circumstances would have overseen and managed its healthcare professionals and medical staff to ensure that they received proper training and updating on the risks associated with feeding cow's milk-based formula to premature infants.

161. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its duty to oversee its healthcare professionals and medical staff who provide patient care, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

162. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital's failure to oversee its healthcare professionals and medical staff on the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

163. As a further direct and proximate result of Penn Medicine and Pennsylvania Hospital's negligent and reckless conduct, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against Penn Medicine and Pennsylvania Hospital, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;

- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of Penn Medicine and Pennsylvania Hospital's conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from Penn Medicine's oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

DEMAND FOR JURY TRIAL

164. Plaintiff hereby demands a jury trial for all claims triable.

Dated: 9/8/2023

Respectfully submitted,

KLINE & SPECTER, P.C.

By: /s/ Timothy A. Burke
Thomas R. Kline, Esq.
Tobias L. Millrood, Esq.
Elizabeth A. Crawford, Esq.
Timothy A. Burke, Esq.
John P. O'Neill, Esq.

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EXHIBIT E

Alice Stills, on her own behalf and as Parent and Natural
Guardian of M.E., a minor

Plaintiffs

v.

MEAD JOHNSON & COMPANY, LLC, et al.

Defendants.

Filed and Attested by the
COURT OF COMMON PLEAS
PHILADELPHIA
2023/02/15 pm

CIVIL DIVISION

MARCH TERM, 2022

NO. 2617

ORDER

AND NOW, this 10th day of March 2023, upon consideration of the

Preliminary Objections of Defendants The Pennsylvania Hospital of the University of
Pennsylvania Health System d/b/a Pennsylvania Hospital and The Trustees of the University of
Pennsylvania d/b/a Penn Medicine to Plaintiffs' Amended Complaint, and any Response thereto,

it is hereby **ORDERED** that the Preliminary Objections are **SUSTAINED**. It is further

ORDERED that all ~~claims~~ *Plaintiff shall file an Amended Complaint* against Defendants the Pennsylvania Hospital of the University of

Pennsylvania Health System d/b/a Pennsylvania Hospital and The Trustees of the University of

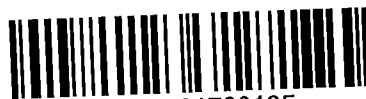
Pennsylvania d/b/a Penn Medicine are hereby **DISMISSED** with prejudice.

*Setting forth their claims
for professional negligence and damages
with specificity.*

BY THE COURT:

[Signature]
J.

220302617-Stills Etal Vs Mead Johnson Nutrition Company Etal



22030261700105

Case ID: 220302617
Control No.: 23096271
Case ID: 220302617
Control No.: 24081574

EXHIBIT F

<p>NOTICE</p> <p>You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so the case may proceed without you and a judgment may be entered against you by the court without further notice for any money claimed in the complaint or for any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.</p> <p>YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW. THIS OFFICE CAN PROVIDE YOU WITH INFORMATION ABOUT HIRING A LAWYER.</p> <p>IF YOU CANNOT AFFORD TO HIRE A LAWYER, THIS OFFICE MAY BE ABLE TO PROVIDE YOU WITH INFORMATION ABOUT AGENCIES THAT MAY OFFER LEGAL SERVICES TO ELIGIBLE PERSONS AT A REDUCED FEE OR NO FEE.</p> <p>Lackawanna Bar Association 233 Penn Avenue Scranton, PA 18503 (570) 961-2714</p>	<p>ADVISO</p> <p>Le han demandado a usted en la corte. Si usted quiere defenderse de estas demandas expuestas en las paginas siguientes, usted tiene veinte (20) dias de plazo al partir de la fecha de la demanda y la notificacion. Hace falta asentar una comparencia escrita o en persona o con un abogado y entregar a la corte en forma escrita sus defensas o sus objeciones a las demandas en contra de su persona. Sea avisado que si usted no se defiende, la corte tomara medidas y puede continuar la demanda en contra suya sin previo aviso o notificacion. Ademias, la corte pueda decidir a favor del demandante y requiere que usted cumpla con todas las provisiones de esta demanda. Usted puede perder dinero o sus propiedades u otros derechos importantes para usted.</p> <p>LLEVE ESTA DEMANDA A UN ABOGADO INMEDIATAMENTE, SI NO TIENE ABOGADO O SI NO TIENE EL DINERO SUFICIENTE DE PAGAR TAL SERVICIO, VAYA EN PERSONA O LLAME POR TELEFONO A LA OFICINA CUYA DIRECCION SE ENCUENTRA ESCRITA ABAJO PARA AVERIGUAR DONDE SE PUEDE CONSEGUIR ASISTENCIA LEGAL.</p> <p>Colegio de Abogados del Lackawanna 233 Penn Avenue, Scranton, PA 18503 (570) 961-2714</p>
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KLINE & SPECTER, P.C.

By:

Tobias L. Millrood, Esq.
Elizabeth A. Crawford, Esq.
Timothy A. Burke, Esq.
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<div style="border: 1px solid black; padding: 10px;"><p>ALICE STILLS, on her own behalf and as Parent and Natural Guardian of M.E., a Minor,</p><p style="text-align: center;"><i>Plaintiff,</i></p><p style="text-align: center;">v.</p><p>MEAD JOHNSON & COMPANY, LLC, MEAD JOHNSON NUTRITION COMPANY, ABBOTT LABORATORIES, THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA d/b/a PENN MEDICINE, and PENNSYLVANIA HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM d/b/a PENNSYLVANIA HOSPITAL,</p><p style="text-align: center;"><i>Defendants.</i></p></div>	<p>: IN THE COURT OF COMMON PLEAS</p> <p>: PHILADELPHIA COUNTY</p> <p>:</p> <p>: CIVIL TRIAL DIVISION</p> <p>:</p> <p>: MARCH TERM 2022</p> <p>: NO. 02617</p> <p>:</p> <p>:</p> <p>:</p> <p>:</p> <p>:</p> <p>:</p> <p>:</p> <p>:</p> <p>:</p> <p>:</p> <p>:</p>
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SECOND AMENDED COMPLAINT

Plaintiff brings this Second Amended Complaint and Demand for Jury Trial (the “Second Amended Complaint”) against Mead Johnson & Company, LLC, Mead Johnson Nutrition Company, and Abbott Laboratories (collectively “the Defendant Manufacturers”), and The Trustees of the University of Pennsylvania d/b/a Penn Medicine and Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital (collectively “Penn

Medicine” or “Pennsylvania Hospital”), together “Defendants.” Plaintiff alleges the following upon personal knowledge as to Plaintiff’s own acts and experiences and upon information and belief, including investigation conducted by Plaintiff’s attorneys, as to all other matters.

I. INTRODUCTION

1. This action arises out of the injuries suffered by a premature infant (the “Injured Infant”) who was given the Defendant Manufacturers’ cow’s milk-based infant feeding products at Pennsylvania Hospital. Pennsylvania Hospital, managed by Penn Medicine, acquired and supplied the Defendant Manufacturers’ products to the Injured Infant and negligently failed to warn of their unreasonably dangerous properties in a reasonable manner. This caused the Injured Infant to develop necrotizing enterocolitis (“NEC”), a life-altering and potentially deadly disease that largely affects premature babies who are given cow’s milk-based feeding products. As a result, the Injured Infant was seriously injured, resulting in long term health effects and accompanying harm to their parent (“the Plaintiff Parent”).

2. Plaintiff brings these causes of action against Defendants to recover for injuries that are the direct and proximate result of the Injured Infant’s consumption of the Defendant Manufacturers’ unreasonably dangerous cow’s milk-based infant feeding products, which were acquired and supplied without adequate warning to the Injured Infant at Pennsylvania Hospital, owned and operated by Penn Medicine.

II. PARTIES

3. Plaintiff Alice Stills is a natural adult person and a resident of Pennsylvania. Ms. Stills is the parent and natural guardian of M.E., a minor. Ms. Stills’s address is 656 N. Conestoga Street, Philadelphia, Pennsylvania 19131.

4. Defendant Mead Johnson Nutrition Company is a corporation, incorporated under the laws

of the State of Delaware. Its principal place of business is Illinois. Defendant Mead Johnson & Company, LLC, is a limited liability company, organized under the laws of the State of Delaware. Its citizenship is that of its sole member, Mead Johnson Nutrition Company. Defendants Mead Johnson Nutrition Company and Mead Johnson & Company, LLC, (together, “Mead”) are manufacturers of cow’s milk-based infant feeding products and market many of these products under the “Enfamil” brand name.

5. Defendant Abbott Laboratories (“Abbott”) is a corporation, incorporated under the laws of the State of Illinois. Its principal place of business is in Illinois. Abbott is a manufacturer of cow’s milk-based infant feeding products and markets many of its products under the “Similac” brand name.

6. Defendant The Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital is a non-profit corporation incorporated and registered to do business under the laws of the Commonwealth of Pennsylvania. Its principal place of business is Philadelphia, Pennsylvania. Pennsylvania Hospital is a registered name of The Pennsylvania Hospital of the University of Pennsylvania Health System. The sole member of The Pennsylvania Hospital of the University of Pennsylvania Health System is The Trustees of the University of Pennsylvania.

7. Defendant The Trustees of the University of Pennsylvania d/b/a Penn Medicine is a non-profit corporation registered to do business in the Commonwealth of Pennsylvania. Its principal place of business is Philadelphia, Pennsylvania. Penn Medicine is a registered name of The Trustees of the University of Pennsylvania.

III. JURISDICTION AND VENUE

8. This Court has jurisdiction in this matter pursuant to 42 Pa. C.S.A. § 931. Defendants

conduct authorized business in the Commonwealth of Pennsylvania. They have sufficient minimum contacts with and purposefully avail themselves of the markets of this Commonwealth. This suit arises out of Defendants' forum-related activities, such that the Court of Common Pleas of Philadelphia County's exercise of jurisdiction would be consistent with traditional notions of fair play and substantial justice.

9. Venue is proper in the Court of Common Pleas of Philadelphia County pursuant to Rules 1006(b), 1006(c)(1), and 2179(a) of the Pennsylvania Rules of Civil Procedure because Defendants are corporations or similar entities that regularly conduct business in Philadelphia County, which is also the county where Plaintiff's causes of action arose, and the county where the occurrences took place out of which Plaintiff's causes of action arose.

10. This action is not subject to the Compulsory Arbitration Program of the Court of Common Pleas of Philadelphia County because the amount in controversy, excluding interest and costs, is in excess of \$50,000.

IV. FACTUAL ALLEGATIONS

M.E.'s NEC Diagnosis

11. M.E. was born premature at Pennsylvania Hospital in Philadelphia, Pennsylvania on September 28, 2007.

12. At birth, M.E.'s gestational age was approximately 28 weeks and he weighed 622 grams, making him an extremely low birth weight infant.

13. Upon information and belief M.E. was fed Similac and/or Enfamil cow's milk-based products by staff at Pennsylvania Hospital from shortly after her birth despite the fact that Pennsylvania Hospital knew or should have known that cow's milk-based products increase the risk of NEC and that human milk decreases the risk of NEC.

14. Specifically, beginning on September 29, 2007, Dr. Thomas Mollen ordered that M.E. was to be fed mother's breast milk which was then fortified with bovine-based human milk fortifier (HMF) in order to be 24 cal/oz, which based upon information and belief was manufactured by Defendant Abbott Laboratories and/or Defendant Mead Johnson.

15. Further, upon information and belief, no later than October 29, 2007, Dr. Mollen revised his nutritional orders to start feeding infant M.E. Abbot's "Special Care" bovine based formula, which M.E. was ultimately fed for a total of 31 days while under the care of Pennsylvania Hospital.

16. On November 2, 2007, M.E. was diagnosed in the Pennsylvania Hospital NIC-U with stage II-B Medical NEC, and thereafter was transferred to Children's Hospital of Philadelphia (CHOP) for management of Medical NEC. M.E. was treated for Medical NEC at CHOP between November 2 to November 8, 2007

17. November 8, 2007, when M.E. was discharged from CHOP and returned to the Pennsylvania Hospital NICU, the treating physicians at the Pennsylvania Hospital NICU revised his nutritional orders to start feeding infant M.E. Abbot's "Neosure" bovine based formula for a total of another 8 days, after which they switched back to Abbott's "Special Care".

18. These feeds all occurred despite the fact that Pennsylvania Hospital knew or should have known that cow's milk-based products, including formula and human milk fortifier, increase the risk of NEC and that human milk can decrease the risk of NEC.

19. On December 5, 2007 M.E. was discharged from the Pennsylvania Hospital NICU, and Plaintiff parent was given the recommendation to continue feeding with Neosure, as well as samples of the product.

20. As a result of the Stage II-B Medical NEC diagnosis, infant M.E. experienced permanent developmental delay, including but not limited to neurodevelopmental impairment (NDI).

Cow's Milk-Based Feeding Products Are Known to Cause NEC

21. NEC is a devastating disease that is the most frequent and lethal gastrointestinal disorder affecting preterm infants. NEC develops when harmful bacteria breach the walls of the intestine, causing portions of the intestine to become inflamed and often to die. Once NEC develops, the condition can progress rapidly from mild feeding intolerance to systemic and fatal sepsis. Up to 30 percent of NEC-diagnosed infants die from the disease.

22. Preterm and low-birth-weight infants are especially susceptible to NEC because of their underdeveloped digestive systems. Extensive scientific research, including numerous randomized controlled trials, has confirmed that cow's milk-based feeding products cause NEC in preterm and low-birth-weight infants, which in turn may lead to other medical complications, surgeries, long-term health problems, and death.

Safer, Nutritionally Superior Alternatives to Cow's Milk-Based Products Exist

23. A range of options are available that allow preterm and low-birth-weight infants to be fed exclusively human milk-based nutrition. For example, in addition to the mother's own milk, an established network delivers pasteurized donor breast milk to hospitals nationwide. Moreover, hospitals have access to shelf-stable formula and fortifiers derived from pasteurized breast milk.

24. A diet based exclusively on breast milk and breast milk fortifiers provides all the nutrition necessary to support premature and low-birth-weight infants without the elevated risk of NEC associated with cow's milk-based products.

25. The Defendant Manufacturers' products not only pose a threat to infants' health, but also displace the human milk they could otherwise receive. This displacement only increases infants' vulnerability to NEC.

26. Human milk-based nutrition nourishes infants while creating a significantly lower risk of

NEC.

27. At the time the Injured Infant was fed the Defendant Manufacturers' products, the science clearly demonstrated to Defendants that these products cause NEC and greatly increase the likelihood that a baby will develop NEC, leading to severe injury and often death.

28. Despite the scientific evidence that the Defendant Manufacturers' cow's milk-based products present a dire threat to the health and development of preterm infants, the Defendant Manufacturers have made no changes to their products or the products' packaging, guidelines, instructions, or warnings. Instead, they have continued to sell their unreasonably dangerous products. In addition, they incentivize hospitals that know the risks to use their products by providing them to the hospital for free or at a significant discount, in order that vulnerable infants and their families will become accustomed to using their products before discharge. And, in fact, the Defendant Manufacturers offer contracts to hospitals—which the hospitals accept—that actually *prevent* the health care providers from offering alternative products—even safer ones—on pain of risking the hospital's advantageous formula pricing strategy.

29. Despite the scientific evidence that the Defendant Manufacturers' cow's milk-based products present a dire threat to the health and development of preterm infants and Pennsylvania Hospital knew or should have known of that threat, staff of Pennsylvania Hospital fed Similac and/or Enfamil cow's milk-based products after her birth instead of mother's human milk and/or donor human milk.

30. Despite the scientific evidence that the Defendant Manufacturers' cow's milk-based products present a dire threat to the health and development of preterm infants and Pennsylvania Hospital knew or should have known of that threat, staff of Pennsylvania Hospital did not properly warn Ms. Wiger of those risks and alternatives to have avoided the cow's milk-based products.

Ms. Stills Discovers Her Claim

31. Because of the Defendants' concealment and misrepresentations, described more fully herein, Ms. Stills did not know, and had no reason to know or suspect, that M.E.'s NEC could have been caused by the Defendant Manufacturers' products.

***Despite Exercising Diligence, a Reasonable Investigation Did Not Reveal and
Would Not Have Revealed a Factual Basis Earlier
Because Defendants Hid the Cause of NEC from Ms. Stills***

32. Despite exercising reasonable diligence, Ms. Stills was unable to have made the discovery earlier via a reasonable investigation because the Defendants in this litigation concealed the wrongful cause of M.E.'s injuries.

33. Amidst the physical and emotional trauma of preterm childbirth, and having her child in the neonatal intensive care unit, shortly after learning of M.E.'s NEC diagnosis, Ms. Stills undertook an investigation into the cause of the NEC by asking the doctors the cause of her NEC.

34. The health care providers at Penn Medicine responded only that M.E. had gotten NEC because he was born premature. Penn Medicine's response did not indicate that her NEC was caused by the Defendant Manufacturers' products.

35. Not one person at Penn Medicine mentioned that the Defendant Manufacturers' formula products could have caused M.E.'s injuries. Penn Medicine's response at the time did not give Ms. Stills any reason to suspect any wrongdoing on the part of the Defendants.

36. Ms. Stills is a layperson with no medical background or training that would have given her any reason to doubt the response she received from her Penn Medicine health care providers at the time.

37. Given that Penn Medicine's health care providers were in charge of the care of her newborn infant, Ms. Stills had no reason to doubt their word.

38. Additionally, the risk of necrotizing enterocolitis was not disclosed on the labeling or packaging of *any* of the Defendant Manufacturers' products.

39. What is more, necrotizing enterocolitis is a disease that can occur in children who are *not* fed the Defendant Manufacturers' products, and the Defendant Manufacturers have worked to mislead parents into a false sense of security about the use of those products. Publicly disseminated materials from each Defendant Manufacturer disguise the role their products play in causing the disease—and affirmatively say, even today, that their products are safe and do not cause NEC. In fact, some publicly disseminated materials from the formula manufacturers even suggest that formula may help *reduce* the risk of this terrible and potentially fatal disease.

40. For example, Abbott's website says that "[t]he specific cause of NEC is unknown, but it's most often seen in very low birth weight premature babies," and that "about 10% of babies who are born prematurely develop NEC." The website suggests that "new preliminary studies" suggest for the first time that "NEC prevention may . . . be possible" with the use of human milk oligosaccharides to "dramatically curb intestinal inflammation" and reduce the risk of NEC. Abbott states that these human milk oligosaccharides are found in "certain Similac formulas" although they are "not currently available in Similac's premature infant formulas."¹ Likewise, the website for Mead Johnson's products states that necrotizing enterocolitis is "one of the most common and serious intestinal disease[s] among premature babies." And it deflects responsibility from Mead Johnson's products: "Necrotizing enterocolitis happens when tissue in the small or large intestine is injured or inflamed."²

¹ The Role of HMOs in Reducing NEC, <https://www.nutritionnews.abbott/pregnancy-childhood/prenatal-breastfeeding/the-promising-role-of-hmos-in-reducing-risk-of-nec/> (last visited July 28, 2023).

² Special Feeding Concerns for Preemies, <https://www.enfamil.com/articles/special-feeding-concerns-for-preemies/> (last visited July 29, 2023).

41. Because of the misleading information distributed by the Defendant Manufacturers, as further detailed *infra*, any research conducted by Ms. Stills immediately after M.E.'s diagnosis, or at any time prior to seeing an advertisement, would not have led a reasonable person to suspect that the Defendant Manufacturers' products could have caused M.E.'s injuries.

42. Ms. Stills also did not know, and had no reason to know or suspect, that Penn Medicine breached its duty of care by distributing the Defendant Manufacturers' products to her. Not only was Ms. Stills unaware that the Defendant Manufacturers' products caused M.E.'s injuries, but the Defendant Manufacturers' distribution agreements with Penn Medicine—which allowed Penn Medicine to secure sweetheart deals for otherwise expensive premature infant formula in exchange for product placement and access to the hospital staff—were also not public or knowable to Ms. Stills, nor could any reasonable investigation outside of litigation have uncovered the terms of those agreements.

Despite Exercising Reasonable Diligence, the Defendants' Fraudulently Concealed the Risks of NEC from Defendant Manufacturers' Products to Divert, Prevent, and Mislead Plaintiff Regarding the Cause of Her Child's NEC Diagnosis

43. In addition to the averments above, the Defendants have acted in concert to fraudulently convey false and misleading information concerning the risk of NEC, and potentially death, caused by Defendant Manufacturers' preterm infant formula products.

44. The Defendants' actions as set forth herein constitute knowing misrepresentation, omission, suppression, and concealment of material facts, made with the intent that Plaintiff would rely upon such concealment, suppression, or omission, in connection with the use of Defendants' preterm infant products.

45. Plaintiff did not know, and could not learn, the truth concerning the uses, risks and benefits of Defendant Manufacturers' preterm infant products due to Defendants' deliberate

misrepresentations and concealment, suppression and omission of material facts and important information regarding the risks of NEC, and potentially death, from the products.

46. Moreover, Defendant Hospital further participated in the intentional concealment—on information and belief, it allowed the Defendant Manufacturers’ sales representatives into its hospital to provide samples and free products that did not warn of their serious dangers, and to provide “education” to its NICU staff that was incomplete as to the true risks of feeding their patients the Defendant Manufacturers’ products.

47. Based upon information and belief, during the relevant time period, Pennsylvania Hospital, Penn Medicine, and the Hospital of the University of Pennsylvania stocked formula products from both Abbott and Mead.

48. Additionally, Defendant Hospital failed to inform Ms. Stills that the Defendant Manufacturers’ products caused Plaintiff’s NEC, even when she directly asked the cause. As noted above, after learning of Plaintiff’s NEC diagnosis, Ms. Stills was understandably concerned about the degrading health of her newborn infant. As any concerned parent would do, Ms. Stills asked Plaintiff’s health care providers at Defendant Hospital why a premature infant like M.E. was suddenly diagnosed with a terrible disease like necrotizing enterocolitis; that is, she asked Defendant Hospital what caused Plaintiff’s injury. But even though Defendant Hospital knew of the increased risk of NEC from formula, it did not disclose that the formula provided to M.E. could increase the risk of NEC to preterm infants, responding only that M.E. had gotten NEC solely because she was born premature. Not one person at the NICU mentioned that the Defendant Manufacturers’ formula products could have been the cause of Plaintiff’s injuries.

49. Defendant Hospital was aware that the Defendant Manufacturers’ products caused NEC in premature infants. Defendant Hospital was also aware that the Defendant Manufacturers did not

provide warnings on their products. However, Defendant Hospital did not warn Ms. Stills of the risks of the products. Instead, and notwithstanding the sweetheart deal Defendant Hospital agreed to in exchange for preterm infant formula at little to no cost, Defendant Hospital repeatedly informed Ms. Stills that it would do everything it could possibly do to keep her infant safe. Though this was clearly not true given the known risks of preterm formula for babies like M.E., it was enough for Ms. Stills to trust that Defendant Hospital was providing preterm formula in the best interest of her child.

50. Defendants' affirmative acts of fraud and concealment, as averred herein, diverted, prevented, and/or mislead Plaintiff from discovering the medical cause of her child's NEC diagnosis.

The Defendant Manufacturers' False and Misleading Marketing Regarding Cow's Milk-Based Infant Products

51. Abbott and Mead have aggressively marketed their cow's milk-based products as medically endorsed and nutritionally equivalent alternatives to breast milk, including prior to the Injured Infant's birth.

52. Abbott's and Mead's marketing approach includes targeting the parents of preterm infants while they are still in the hospital with messages that the Defendant Manufacturers' cow's milk formulas and fortifiers are necessary for the growth and development of their vulnerable children. Often these tactics implicitly discourage mothers from breastfeeding, which reduces the mother's supply of breast milk. None of the Defendant Manufacturers' marketing materials, including their promotional websites, reference the science showing how significantly their products increase the risk of NEC.

53. For example, upon information and belief, Mead creates information booklets for parents of premature infants to help answer some of their questions and concerns about having a premature

infant in the NICU that it provides to hospitals for dissemination to parents. While Mead's booklets explain feeding options for premature infants, including formula, they do not mention that Mead's premature formula and fortifier products increase the risk of premature infants developing necrotizing enterocolitis. Instead, the booklets advise parents that sometimes a combination of breast milk and formula may be best and that premature infants will be happy and healthy or nourished and healthy regardless of whether they are receiving breast milk or formula.

54. Similarly, upon information and belief, Abbott publishes a pediatric nutrition product guide that is available online for anyone, including parents, to access wherein Abbott advises that "human milk alone does not meet all the nutritional needs of preterm infants" and that the formulations of its products, which are based on decades of research and scientific publications, are "specially designed to meet the nutritional requirements of preterm infants and can be fed with confidence to most of the preterm infants in the NICU." Nowhere in its product guide does Abbott reference that its products increase the risk of necrotizing enterocolitis.

55. Abbott also has a consumer-facing website accessible to anyone online, including parents, that specifically discusses nutrition for premature infants, wherein Abbott tells parents of premature infants that "your baby's nutrient needs are greater than what breast milk alone can provide" and that a "human milk fortifier" may be added to breastmilk to "add[] proteins, vitamins, and minerals to help support a preemie's high nutrition needs for growth and development." Nowhere in its discussion of preterm infant fortifiers or formulas does Abbott state that its products increase the risk of necrotizing enterocolitis or that they pose more of a risk than just providing preterm infants with breast milk only. Nor does Abbott disclose that the "human milk fortifier" is actually a cow's milk based product and not a human milk-based product, which misleads consumers.

56. Upon information and belief, both Mead and Abbott also provide materials and programs to the hospitals and the physicians and medical staff who are treating premature infants about the manufacturers' preterm products. Upon information and belief, these materials represent that the manufacturers' preterm products are safe and necessary for preterm infants. Mead and Abbott rely on the physicians and medical staff to not only use their products in the NICU, but to convey these messages to the parents of premature infants in their care.

57. Undoubtedly aware of the impact of their advertising, the Defendant Manufacturers, along with other formula manufacturers, are willing to spend massive sums to disseminate their message.

58. Recognizing the abuse and dangers of infant formula marketing, in 1981, the World Health Assembly—the decision-making body of the World Health Organization—developed the International Code of Marketing of Breast-milk Substitutes (“the Code”), which required companies to acknowledge the superiority of breast milk, the negative effect on breastfeeding of introducing partial bottle-feeding, and the difficulty of reversing the decision not to breastfeed. The Code also forbade advertising or other forms of promotion of formula to the general public, as well as providing sample products to mothers or members of their families.

59. While Abbott and Mead acknowledge the Code on their websites and claim to support the effort to encourage mothers to breastfeed for as long as possible, this is little more than lip service. Instead, the Defendant Manufacturers' aggressive marketing exploits new parents' darkest fears—that the nutrition they are supplying to their child will not provide the best chance of survival—while wholly failing to warn that their products come with a significantly increased risk of NEC.

60. For example, Abbott's website, on a page titled “Infant Formula Marketing,” states: “We agree with the World Health Organization that breastfeeding provides the best nutrition for babies, and we support its goal to increase breastfeeding. We also recognize that for infants who aren't

breastfed—for medical reasons or otherwise—infant formula is the only appropriate, safe alternative to meet babies’ nutritional needs.” This statement ignores the existence of donor milk, as well as human milk-based formula.

61. Abbott markets and sells multiple products specifically targeting preterm and low-birthweight infants, including Liquid Protein Fortifier, Similac NeoSure, Similac Human Milk Fortifiers, Similac Special Care 20, Similac Special Care 24, Similac Special Care 24 High Protein, and Similac Special Care 30. In advertising these products, Abbott emphasizes the products’ purported ability to assist underdeveloped babies in reaching their growth targets. For example, on the since-edited webpage regarding Similac NeoSure, Abbott noted: “Your premature baby didn’t get her full 9 months in the womb, so her body is working hard to catch up. During her first full year, feed her Similac NeoSure, a nutrient-enriched formula for babies who were born prematurely, and help support her development.” Yet, no mention was made of the accompanying significantly increased risk of NEC. At some point, the website was edited to remove this statement. However, upon information and belief, the statement remained on the website until at least December 2020.

62. Abbott’s website also contains product information and a downloadable guide for each of its products specifically targeting preterm and low-birth-weight infants, including Liquid Protein Fortifier, Similac NeoSure, Similac Human Milk Fortifiers, Similac Special Care 20, Similac Special Care 24, Similac Special Care 24 High Protein, and Similac Special Care 30. None of these pages or guides contain any mention of NEC or that the products specifically increase the risk of NEC. Indeed, a search of Abbott’s website for “necrotizing enterocolitis” returns no hits. Instead, Abbott states that “enteral feeding” – which includes breast milk and donor milk – have been “associated with” things like “[s]pitting up, abdominal distension” or “other signs of

intestinal dysfunction.” This statement is entirely misleading, as it improperly indicates that the risk of things like “spitting up” are the same for premature infants using Abbott’s products and premature infants receiving breast milk or donor milk, equates formula to non-cow’s milk-based feeding options like breast milk and donor milk, fails to mention NEC, and minimizes the risk of its products.

63. Mead markets and sells multiple products specifically targeting premature infants, including Enfamil NeuroPro EnfaCare Infant Formula, Enfamil Premature Infant Formula 24 Cal High Protein, Enfamil Premature Infant Formula 30 Cal with Iron, Enfamil Premature Infant Formula 24 Cal with Iron, Enfamil Premature Infant Formula 20 Cal with Iron, Enfamil 24 Cal Infant Formula, and Enfamil Human Milk Fortifier (acidified liquid and powder). In advertising these products, Mead emphasizes the purported similarities between its formula and breast milk, while failing to include any information about the nutritional deficits and dangers that accompany formula use. For example, the since-edited webpage for Enfamil Enfacare stated: “Premature babies fed Enfamil® formulas during the first year have achieved catch-up growth similar to that of full term, breastfed infants” and noted that Enfamil formulas include “expert-recommended levels of DHA and ARA (important fatty acids found naturally in breast milk) to support brain and eye development.”

64. One Enfamil advertisement, introducing a new product line called Enfamil NeuroPro, is entirely focused on favorably comparing Enfamil’s formula to breast milk, without any mention of the product’s extreme risks. Indeed, the terms “human milk” and “breast milk” are used 13 times in the advertisement, including in such statements as “for decades human milk has inspired the advancements in Enfamil formulas and now through extensive global research, we are taking an even closer look at human milk” and “only Enfamil NeuroPro has a fat blend of MFGM and DHA

previously found only in breast milk.” The webpage for the product has made similar manipulative claims, stating “Enfamil is backed by decades of breast milk research and multiple clinical studies” and it claims that “to create our best formulas, we collaborated on some of the most extensive breast milk studies to date[.]”

65. Mead’s website also contains product information for each of its products specifically targeting preterm and low-birth-weight infants, including Enfamil NeuroPro EnfaCare Infant Formula, Enfamil Premature Infant Formula 24 Cal High Protein, Enfamil Premature Infant Formula 30 Cal with Iron, Enfamil Premature Infant Formula 24 Cal with Iron, Enfamil Premature Infant Formula 20 Cal with Iron, Enfamil 24 Cal Infant Formula, and Enfamil Human Milk Fortifier (acidified liquid and powder). None of these pages contain any mention of NEC or that the products specifically increase the risk of NEC. Indeed, a search of Mead’s website for “necrotizing enterocolitis” returns no hits. Instead, Mead advertises on its website that it “has led the way in developing safe, high-quality, innovative products” – including preterm products – “to help meet the nutritional needs of infants.”

66. Formula manufacturers have long used their relationships with hospitals and the discharge process to encourage parents to substitute formula for breast milk. They offer free or reduced-cost formula to hospitals for use with infants before discharge. And they offer free formula, coupons, and even entire gift baskets to parents before their infants’ discharge from the NICU or hospital.

67. Here, S.P. was discharged from CHOP with the recommendation to continue use of Abbott’s Similac Special Care 24 formula.

68. Through this early targeting, the Defendant Manufacturers create brand loyalty under the guise of a “medical blessing,” in hopes that new parents continue to use formula after they leave the hospital, resulting in increased expense for parents, significantly increased risk for babies, and

increased profit for the Defendant Manufacturers. The Defendant Manufacturers' giveaways and gift baskets send confusing signals to mothers who are simultaneously being encouraged to breastfeed by their healthcare professionals, and they have been shown to negatively impact breastfeeding rates.

69. Further, when the Defendant Manufacturers recognized a shift in the medical community towards an exclusive breast milk-based diet for premature infants, Abbott developed a product called "Similac Human Milk Fortifier," and Mead developed "Enfamil Human Milk Fortifier." These names are misleading in that they suggest that the products are derived from breast milk, when, in fact, they are cow's milk-based products. The packaging appears as:



70. The Defendant Manufacturers have designed powerful misleading marketing campaigns to deceive parents into believing that: (1) cow's milk-based products are safe, including for preterm infants; (2) cow's milk-based products are equal, or even superior, substitutes to breast milk; (3) cow's milk-based products are necessary for proper growth and development of preterm infants; and (4) physicians consider the Defendant Manufacturers' cow's milk-based products to be a first choice. This marketing scheme is employed despite all Defendants knowing of and failing to warn

of the extreme risk of NEC and death that cow's milk-based products pose to preterm infants like the Injured Infant.

71. The Defendant Manufacturers have also designed powerful marketing campaigns to both the general public and health care providers at hospitals like Pennsylvania Hospital. The Defendant Manufacturers know that sales made to hospitals are key drivers of brand loyalty, and thus are a key opportunity to drive better downstream business—*i.e.*, retail purchases by parents after they have left the hospital. On information and belief, the Defendant Manufacturers know that the formula products used in a hospital's NICU are related to getting and keeping the overall hospital contracts. And the Defendant Manufacturers know that, just like any celebrity endorsement, when mothers of newborn infants see medical professionals using a certain brand, the mothers are more likely to continue to purchase that same brand after discharge. The Defendant Manufacturers are thus heavily motivated to ensure that NICU departments are using their products.

72. Abbott and Mead Johnson focus their sales teams and training heavily on hospital NICU departments. They train their sales representatives how to increase the number of babies on their formula, and they emphasize the need to be the dominant formula manufacturer in the NICU so they can own that profitable ground and secure a great return on their substantial investment in NICU formula and other products.

73. To leverage hospitals' NICUs and secure babies in the hospital and at retail, the Manufacturer Defendants pull out all the stops to convince hospitals, including Defendant Hospital, to purchase their products. For example: Abbott and Mead Johnson provide samples of their products to hospitals for free.

74. On information and belief, to get the hospitals on board with supplying their formula for premature infants, Abbott and Mead Johnson work with hospitals to secure contracts that have special pricing discounts if a certain level of the formula-fed babies in the hospital receive just that one manufacturer's products; similar to a restaurant being a Coke or Pepsi restaurant. And notwithstanding the increased risk of the Defendant Manufacturers' products for the hospitals' most fragile patients—the preterm infants—the decision makers at these hospitals seek out these types of contracts to better the hospitals' own bottom lines.

75. On information and belief, Abbott and Mead Johnson also seek promises and/or assurances that the full range of health care providers at the hospitals, including the nurse practitioners and other staff who would pull the infant formula off the shelf, are grabbing the respective company's own formula products to give to the preterm infants. The goal of this tactic was to ensure that the Defendant Manufacturers and key people at the hospital would be sending a shared message that the preterm infant formula products were safe and without risk, even though that is not what the science said.

76. On information and belief, Abbott and Mead Johnson also seek promises and/or assurances that the full range of health care providers at the hospitals, including the nurse practitioners and other staff who would pull the infant formula off the shelf, are grabbing the respective companies' own formula products to give to the preterm infants. The goal of this tactic was to ensure that the Defendant Manufacturers and key people at the hospital would be sending a shared message that the preterm infant formula products were safe and without risk, even though that is not what the science said.

77. On information and belief, prior to M.E.'s birth, Abbott sent sales representatives to Defendant Hospital. Those sales representatives provided information about Abbott's products to

Defendant Hospital's staff via conversations, presentations, and written pamphlets. This information indicated that Abbott's products were safe to give to preterm infants like M.E. Abbott maintains call logs that detail which sales representatives visited the hospitals, which days they visited, and which products they discussed. These sales representatives did not disclose that Abbott's products could cause NEC in preterm infants.

78. On information and belief, prior to M.E.'s birth, Mead Johnson sent sales representatives to Defendant Hospital. Those sales representatives provided information about Mead Johnson's products to Defendant Hospital's staff via conversations, presentations, and written pamphlets. This information indicated that Mead Johnson's products were safe to give to preterm infants like M.E. Mead Johnson maintains call logs that detail which sales representatives visited the hospitals, which days they visited, and which products they discussed. These sales representatives did not disclose that Mead Johnson's products could cause NEC in preterm infants.

79. Mead Johnson and Abbott believed and intended that the misrepresentations that its sales representatives shared with Defendant Hospital would be used to make feeding decisions for preterm infants like M.E.

The Defendant Manufacturers' Inadequate Warnings

80. Although Mead promotes an aggressive marketing campaign designed to convince parents that its cow's milk-based products are safe and necessary for the growth of a premature infant, the product is in fact extremely dangerous for premature infants. Enfamil products significantly increase the chances of a premature infant developing potentially fatal NEC.

81. The Enfamil products Mead markets specifically for premature infants are commercially available at retail locations and online. No prescription is necessary.

82. Despite knowing of the risk of NEC, the packaging of Mead's products does not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated

with Mead's products, or of the magnitude of this increased risk. Mead likewise did not provide instructions or guidance for how to avoid NEC.

83. Mead cites no medical literature or research to guide the use of its products.

84. Despite knowing of the risk of NEC, Mead did not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with its products, or of the magnitude of this increased risk. Mead likewise did not provide instructions or guidance for how to avoid NEC.

85. Mead deceived the public, parents, physicians, other medical professionals, and medical staff into believing that Enfamil products were a safe and necessary alternative, supplement and/or substitute to breast milk.

86. Mead Johnson failed to provide, and continues to fail to provide, a full accounting of the risk of NEC as documented, by underrepresenting and misrepresenting the risk to the public and the medical community.

87. Despite knowing that its products were being fed to premature infants, often without the parents' informed consent, Mead failed to require or recommend that medical professionals inform parents of the significant risk of NEC or to require that parental consent be obtained prior to the products being fed to their babies. Like Mead, Abbott promotes an aggressive marketing campaign designed to make parents believe that its products are safe and necessary for the growth of premature infants, despite the products in fact being extremely dangerous for premature infants. Abbott's products significantly increase the chances of a premature infant getting potentially fatal NEC.

88. The products Abbott markets specifically for premature infants are available at retail locations and online. No prescription is necessary.

89. Despite knowing of the risk of NEC, Abbott did not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with its products, or of the magnitude of this increased risk. Abbott likewise did not provide instructions or guidance for how to avoid NEC.

90. Abbott deceived the public, parents, physicians, other medical professionals, and medical staff into believing that its products were a safe and necessary alternative, supplement and/or substitute to breast milk.

91. Despite knowing of studies documenting an increased risk of NEC from its products, Abbott did not act to make parents or the medical community aware of those risks, and instead took steps to conceal or prevent those risks from becoming public. Despite knowing that its products were being fed to premature infants, often without the parents' informed consent, Abbott failed to require or recommend that medical professionals inform parents of the significant risk of NEC or to require that parental consent be obtained prior to the products being fed to their babies.

Penn Medicine's Failure to Warn

92. On information and belief, Penn Medicine, which operates Pennsylvania Hospital, was aware of the significantly increased risk of NEC and death associated with providing Abbott's and Mead's cow's milk-based products to its premature infant patients. It knew or should have known that feeding these cow's milk-based products can cause NEC in premature infants who otherwise would not have developed this devastating condition. It also knew or should have known that human milk decreases the risk of NEC for premature infants. However, instead of warning of the dangers, or supplying human milk-based feeding products to preterm infants like the Injured Infant, Penn Medicine has continued to source, distribute, and supply the Defendant Manufacturers' products in its hospitals without any adequate warning.

93. To that end, Penn Medicine has participated in studies designed to increase the use of donor milk while, at the same time, reducing formula feeding in neonates. The University of Pennsylvania School of Nursing, an affiliate of Penn Medicine, has conducted extensive research into the risks associated with feeding formula to premature infants. It recently partnered with the National Institute of Nursing Research to publish clinical determinations based on its experience “changing hospital systems and influencing policy,” and its findings were unequivocal:

This is what we know about the science of human milk: it reduces the risk of necrotizing enterocolitis, reduces the risk of infection, [and] creates greater enteral feed tolerance and more rapid weaning from intravenous nutrition. . . .

94. Other Penn Medicine research has similarly concluded that “[h]uman milk decreases the incidence and severity of . . . necrotizing enterocolitis (NEC).”

95. Given it was known that human milk decreases the incidence and severity of NEC, it was also known or should have been known that cows milk-based formula increases the incidence and severity of NEC.

96. Penn Medicine also purports to adhere to the tenets of the “Baby Friendly Hospital Initiative,” which seeks to increase rates of breastfeeding initiation, exclusivity, and diet duration. The “Baby Friendly Hospital Initiative” specifically targets a reduction in the rates of NEC in preterm infants by encouraging implementation of exclusive breast milk diets among new mothers. Although Pennsylvania Hospital has maintained its “Baby Friendly” designation for years, it has not eliminated or restricted the use of formula or fortifier for preterm infants in its hospitals.

97. Given it was known since at least the early 2000s, and as far back as the 1990s, that human milk decreases the incidence and severity of NEC, it was also known or should have been known that cows milk-based formula increases the incidence and severity of NEC.

98. Penn Medicine also purports to adhere to the tenets of the “Baby Friendly Hospital Initiative,” which seeks to increase rates of breastfeeding initiation, exclusivity, and diet duration.

The “Baby Friendly Hospital Initiative” specifically targets a reduction in the rates of NEC in preterm infants by encouraging implementation of exclusive breast milk diets among new mothers. Although Pennsylvania Hospital has maintained its “Baby Friendly” designation for years, it has not eliminated or restricted the use of formula or fortifier for preterm infants in its hospitals.

99. Finally, medical providers and staff at Penn Medicine have acknowledged the risks associated with providing the Defendant Manufacturers’ cow’s milk-based products to premature infant patients instead of breast milk-based nutrition. In an internal newsletter from 2012 touting donor milk programs, Penn Medicine acknowledged the benefits of a human milk-based diet, quoting a staff lactation consultant:

Donor milk is not inexpensive. It costs about \$4.25 per ounce, but the return on investment is huge. “Preemies given mother’s milk get discharged three to four days sooner and also have a six to 10 times lower risk of getting a gastrointestinal complication called necrotizing enterocolitis,” Carpenter said, adding that the infection can cost up to \$250,000 to treat. The average cost to provide a preemie with donor milk: \$125.

100. These statements demonstrate that Penn Medicine knew or should have known of the high increased risk of NEC for premature infants posed by the Defendant Manufacturers’ products.

101. Although Penn Medicine knew or should have known of the serious danger of the Defendant Manufacturers’ products, it has continued to purchase, supply, and distribute these products to preterm infants without providing full and adequate warnings of the attendant risks to parents, healthcare professionals, and other medical staff at its relevant facilities. As a result, the Injured Infant was fed the Defendant Manufacturers’ cow’s milk-based products at Pennsylvania Hospital, causing their injuries. This occurred even though hospitals across the country, including Pennsylvania Hospital, warn and obtain consent from parents before providing other safer forms of nutrition, such as donor breast milk.

102. Penn Medicine's failure to warn of the risks posed by the Defendant Manufacturers' products is entrenched (and compounded) by the financial benefits it accrues from its relationships with the Defendant Manufacturers. On information and belief, it has received the Defendant Manufacturers' cow's milk-based products for free and/or at a significant discount, and has granted their sales representatives access to its healthcare professionals and medical staff. These sales representatives have provided deceptive information that Penn Medicine reasonably knew or should have known would ultimately reach parents through those staff. This arrangement dovetails with the Defendant Manufacturers' own marketing strategies" and use of salespersons.

Safer Alternative Designs

103. The Defendant Manufacturers' cow's milk-based products made specifically for premature infants are unreasonably unsafe for those infants. The Defendant Manufacturers could have used pasteurized breast milk instead of cow's milk in their products, which would have produced a safer product.

104. Prolacta Bioscience manufactures and sells breast milk-based feeding products, specifically designed for preterm infants, which contain no cow's milk. This alternative design provides all the necessary nutrition for growth and development that cow's milk-based products provide, without the same unreasonably dangerous and deadly effects.

105. On information and belief, Abbott and Mead were aware of the significantly increased risk of NEC and death associated with their cow's milk-based products, and instead of warning of the dangers, or removing them altogether, Abbott and Mead have continued to use cow's milk as the foundation of their products.

CAUSES OF ACTION
COUNT I: STRICT LIABILITY FOR DESIGN DEFECT
(Against Abbott and Mead)

106. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

107. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to manufacture, sell, and distribute their products in a manner that was not unreasonably dangerous.

108. Abbott and Mead also owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to manufacture, sell, and distribute their products in a manner that was merchantable and reasonably suited for their intended use.

109. Abbott and Mead knew that their products would be used to feed premature infants like the Injured Infant and knew (or reasonably should have known) that use of their cow's milk-based products significantly increased the risk of NEC, serious injury, and death, and that such use was therefore unreasonably dangerous to premature infants, not reasonably suited for the use intended, not merchantable, and had risks that exceeded a reasonable buyer's expectations. Nonetheless, they continued to sell and market their defective products as appropriate for premature infants.

110. The Injured Infant ingested Abbott and/or Mead's unreasonably dangerous cow's milk-based products. The risks of feeding those products to the Injured Infant outweighed the benefits. An ordinary consumer would not expect those products to carry a significant risk of serious injury and death from NEC.

111. Abbott and Mead knew (or reasonably should have known) that breast milk-based nutrition did not carry the same risks of NEC, serious injury, and death that their products do.

112. Abbott's and Mead's products contained cow's milk at the time they left the manufacturing

facility.

113. Abbott and Mead did not develop a human-milk based product that was safer for premature infants and did not reformulate their products to reduce the risk of NEC, serious injury, and death, even though doing so was economically and technologically feasible and even though pasteurized breast milk was an available alternative.

114. Abbott's and/or Mead's products were fed to the Injured Infant, which caused and/or increased the risk of their NEC and injuries.

115. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational

limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;

- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT II: STRICT LIABILITY FOR FAILURE TO WARN
(Against Abbott and Mead)**

116. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

117. Abbott and Mead, as the manufacturers and/or sellers of the infant products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide adequate warnings or instructions about the dangers and risks associated with the use of their products with preterm infants, specifically including but not limited to the risk of NEC, serious injury, and death.

118. Abbott's and Mead's duty to warn is part of their general duty to design, manufacture, and sell their infant products in a manner that is reasonably safe for their foreseeable uses. By designing their products with cow's milk-based ingredients, Abbott and Mead undertook a duty to warn of the unreasonable risk of harm posed by those ingredients, specifically including the significantly increased risk of NEC, severe injury, and death. The failure to warn makes the products at issue in this litigation unreasonably dangerous.

119. Specifically, Abbott and Mead breached their duty to warn of the foreseeable risks of the infant products at issue in this litigation because they knew or should have known that their cow's milk-based premature infant products would be fed to premature infants like the Injured

Infant, and that their products might cause the Injured Infant to develop NEC, severe injury, or death, yet they failed to provide adequate warnings of those risks. Among other risks, the Defendant Manufacturers:

- a. Failed to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death for the Injured Infant; and/or
- b. Failed to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or
- c. Inserted warnings and instructions on their products that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC and death; and/or
- d. "Black box"-type warning that their cow's milk-based products are known to significantly increase the risk of NEC and death when compared to breast milk in premature infant; and/or
- e. Failed to disclose well-researched and well-established studies that linked cow's milk-based products to NEC and death in premature infants; and/or
- f. Failed to insert a warning or instruction to healthcare professionals and other medical staff in the hospital that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risks; and/or
- g. Failed to provide a warning in a method reasonably calculated or expected to reach the parents of newborns, like the Plaintiff Parent; and/or
- h. Failed to provide statistical evidence showing the magnitude of increased risk of

NEC in premature infants associated with cow's milk-based products.

120. Abbott's and Mead's products contained cow's milk at the time they left the manufacturing facility.

121. As a direct and proximate result of the inadequacy of the warnings and the pervasive marketing campaigns suggesting the safety and necessity of the Defendant Manufacturers' products, the Injured Infant were fed cow's milk-based products, which caused and/or increased risk of their developing NEC.

122. The unwarned-of risks are not of a kind that an ordinary consumer would expect. Had physicians and medical staff known of the extreme risk associated with feeding premature infants cow's milk-based formula, they would not have fed the Injured Infant those products. Had the Plaintiff Parent known of the significant risks of feeding the Injured Infant cow's milk-based formula, they would not have allowed such products to be fed to the Injured Infant.

123. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue,

and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;

- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendants Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT III: NEGLIGENCE
(Against Abbott and Mead)**

124. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

125. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to exercise reasonable care to design, test, manufacture, inspect, and distribute a product free of unreasonable risk of harm to users, when such products are used in their intended manner and for their intended purpose.

126. At all times relevant to this action, the Injured Infant's healthcare professionals and medical staff used the products at issue in their intended manner and for their intended purpose.

127. Abbott and Mead, directly or indirectly, negligently, and/or defectively made, created, manufactured, designed, assembled, tested, marketed, sold, and/or distributed the cow's milk-based infant products at issue in this litigation and thereby breached their duty to the general public and the Plaintiff Parent.

128. Specifically, although Abbott and Mead knew or reasonably should have known at the time of production that their cow's milk-based infant products significantly increased the risk of NEC, serious injury, and death, they failed to act in a reasonably prudent manner and breached their duty by:

- a. Failing to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death for the Injured Infant; and/or
- b. Failing to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or
- c. Inserting warnings and instructions that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC and death; and/or
- d. Failing to insert a large and prominent "black box"-type warning that their cow's milk-based products are known to significantly increase the risk of NEC and death when compared to breast milk in premature infants; and/or
- e. Failing to provide well-researched and well-established studies that linked cow's milk-based products to NEC and death in premature infants; and/or
- f. Failing to insert a warning or instruction to healthcare professionals and other medical staff in the hospital that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risks; and/or
- g. Failing to provide a warning in a method reasonably calculated/expected to reach the parents of newborns, like the Plaintiff Parent; and/or

- h. Failing to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products.

129. In addition, although Abbott and Mead knew or reasonably should have known at the time of production that their cow's milk-based products significantly increased the risk of NEC, serious injury, and death, they failed to act in a reasonably prudent manner and breached their duty by failing to perform the necessary process of data collection, detection, assessment, monitoring, prevention, and reporting or disclosure of adverse outcomes in infants who ingest their products.

130. As a direct and proximate result of the Defendant Manufacturers' failure to act in a reasonably prudent manner and their breach of duty, the Injured Infant was fed cow's milk-based products, which caused and/or increased the risk of their developing NEC.

131. Had Abbott and Mead satisfied their duties to the consuming public in general, the Injured Infant would not have been exposed to their unreasonably dangerous cow's milk-based products.

132. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs

related to medical or mental health treatment which have or may be recommended;

- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendants Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT IV: INTENTIONAL MISREPRESENTATION
(Against Abbott and Mead)**

133. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

134. At all times relevant to this action, the Injured Infant consumed the Defendant Manufacturers' products in their intended manner and for their intended purpose.

135. Abbott and Mead, as the manufacturers and/or sellers of the infant products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide truthful, accurate, fulsome information about the risks and benefits of using their products when used in the intended manner and for the intended purpose.

136. Abbott and Mead breached their duty through misrepresentations made to consumers in their advertising and promotional materials, as described in previous paragraphs and incorporated herein, each of whom were foreseeable and intended recipients of this information.

137. Specifically, upon information and belief, Abbott and Mead made the following false statements of material fact on an ongoing and repeated basis to the public, including patient consumers, and parents like Plaintiff Parent and prior to the time the Injured Infant was fed their

products:

- a. That their cow's milk-based products were safe and beneficial for premature infants when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or
- b. That their cow's milk-based products were necessary to the growth and nutrition of premature infants, when they knew or should have known that their products were not necessary to achieve adequate growth; and/or
- c. That their products have no serious side effects, when they knew or should have known the contrary to be true; and/or
- d. That cow's milk-based products were safe for premature infants; and/or
- e. That cow's milk-based products were necessary for optimum growth; and/or
- f. That cow's milk-based products were similar or equivalent to breast milk; and/or
- g. That their products were safe and more like breast milk than other infant products and that they had removed the harmful ingredients of cow's milk when, in fact, the cow's milk in their products was still capable of causing NEC, serious injury, and death; and/or
- h. That their products were safe for and provided better nutrition and growth to premature infants than donor milk, a non-cow's milk-based alternative to breast milk; and/or
- i. That their products can fed with confidence to most of the preterm infants in the NICU and/or that premature infants would be happy and health or nourished and health on their products; and/or
- j. That their products were based on up-to-date science, which made them safe for

premature infants; and/or

- k. Omitting the material fact that their products significantly increased the risk of NEC in premature infants, including omitting this material fact from their publicly available product information, marketing materials, and websites..

138. Abbott and Mead had actual knowledge, or, at a minimum, a reckless indifference, to whether the aforementioned misrepresentations were false.

139. In addition to the above, Abbott and Mead, upon information and belief, also made the following false statements of material fact to Plaintiff Parent:

- a. Omitting from coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent that their products significantly increased the risk of NEC in premature infants; and/or
- b. Omitting from the packaging and labeling of their products provided to Injured Infant that their products significantly increased the risk of NEC in premature infants; and/or
- c. Representing that their cow's milk-based products were safe and beneficial for premature infants on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or
- d. Representing that their cow's milk-based products were safe and beneficial for premature infants on the packaging and labeling of their products provided to Injured Infant when they knew or should have known that their products were

unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or

- e. Representing that their cow's milk-based products were necessary to the growth and nutrition of premature infants on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent when they knew or should have known that their products were not necessary to achieve adequate growth; and/or
- f. Representing that their cow's milk-based products were necessary to the growth and nutrition of premature infants on the packaging and labeling of their products provided to Injured Infant when they knew or should have known that their products were not necessary to achieve adequate growth; and/or
- g. Representing that their cow's milk-based products were similar or equivalent to breast milk on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent; and/or
- h. Representing that their cow's milk-based products were similar or equivalent to breast milk on the packaging and labeling of their products provided to Injured Infant; and/or
- i. Representing that their cow's milk-based products could be fed with confidence to premature infants and/or that premature infants would be healthy regardless of whether they were fed their cow's milk-based products or breast milk on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent; and/or

- j. Representing that their cow's milk-based products could be fed with confidence to premature infants and/or that premature infants would be healthy regardless of whether they were fed their cow's milk-based products or breast milk on the packaging and labeling of their products provided to Injured Infant; and/or
- k. Representing that their cow's milk-based products have no serious side effects on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent when they knew or should have known the contrary to be true; and/or
- l. Representing that their cow's milk-based products have no serious side effects on the packaging and labeling of their products provided to Injured Infant when they knew or should have known the contrary to be true; and/or
- m. Representing that their cow's milk-based products were similar or equivalent to breast milk on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent when they knew or should have known the contrary to be true; and/or
- n. Representing that their cow's milk-based products were similar or equivalent to breast milk on the packaging and labeling of their products provided to Injured Infant when they knew or should have known the contrary to be true; and/or
- o. Representing that their cow's milk-based products were safe for premature infants on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent; and/or
- p. Representing that their cow's milk-based products were safe for premature infants on the packaging and labeling of their products provided to Injured Infant; and/or

- q. Representing that their cow's milk-based products were necessary for optimum growth on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent; and/or
- r. Representing that their cow's milk-based products were necessary for optimum growth on the packaging and labeling of their products provided to Injured Infant; and/or
- s. Representing that their products were based on up-to-date science, which made them safe for premature infants on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent; and/or
- t. Representing that their products were based on up-to-date science, which made them safe for premature infants on the packaging and labeling of their products provided to Injured Infant.

140. The Plaintiff Parent was not aware that these misrepresentations were false and justifiably relied on them. The Defendant Manufacturers' misrepresentations induced the Plaintiff Parent to allow their children to be fed Abbott's and Mead's infant products, in reliance on all the messaging they received about formula feeding, including, directly or indirectly, the Defendant Manufacturers' messaging. Had Abbott and Mead not committed these intentional misrepresentations, the Injured Infant would not have been exposed to the Defendant Manufacturers' unreasonably dangerous cow's milk-based products.

141. As a direct and proximate result, Abbott's and Mead's products were fed to the Injured Infant, which caused and/or increased risk of their developing NEC and subsequent injuries.

142. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss

of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT V: NEGLIGENT MISREPRESENTATIONS
(Against Abbott and Mead)**

143. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

144. At all times relevant to this action, the Injured Infant consumed the products at issue in

their intended manner and for their intended purpose.

145. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide truthful, accurate, and complete information about the risks and benefits of using their products when used in the intended manner and for the intended purpose.

146. In the course of their business, Abbott and Mead breached their duty through misrepresentations made to consumers in their advertising and promotional materials, as described in previous paragraphs and incorporated herein, each of whom were foreseeable recipients of this information.

147. Specifically, upon information and belief, Abbott and Mead made the following false statements of material fact on an ongoing and repeated basis to the public, including consumers, and parents like Plaintiff Parent and prior to the time the Injured Infant was fed their products:

- a. That their cow's milk-based products were safe and beneficial for premature infants when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or
- b. That their cow's milk-based products were necessary to the growth and nutrition of premature infants, when they knew or should have known that their products were not necessary to achieve adequate growth; and/or
- c. That their products have no serious side effects, when they knew or should have known the contrary to be true; and/or
- d. That cow's milk-based products were safe for premature infants; and/or
- e. That cow's milk-based products were necessary for optimum growth; and/or
- f. That cow's milk-based products were similar or equivalent to breast milk; and/or

- g. That their products were safe and more like breast milk than other infant products and that they had removed the harmful ingredients of cow's milk when, in fact, the cow's milk in their products was still capable of causing NEC, serious injury, and death; and/or
- h. That their products were safe for and provided better nutrition and growth to premature infants than donor milk, a non-cow's milk-based alternative to breast milk; and/or
- i. That their products can be fed with confidence to most of the preterm infants in the NICU and/or that premature infants would be happy and healthy or nourished and health on their products; and/or
- j. That their products were based on up-to-date science, which made them safe for premature infants; and/or
- k. Omitting the material fact that their products significantly increased the risk of NEC in premature infants, including omitting this material fact from their publicly available product information, marketing materials, and websites.

148. In addition to the above, Abbott and Mead, upon information and belief, also made the following false statements of material fact to Plaintiff Parent.

- a. Omitting from coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent that their products significantly increased the risk of NEC in premature infants; and/or
- b. Omitting from the packaging and labeling of their products provided to Injured Infant that their products significantly increased the risk of NEC in premature infants; and/or

- c. Representing that their cow's milk-based products were safe and beneficial for premature infants on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or
- d. Representing that their cow's milk-based products were safe and beneficial for premature infants on the packaging and labeling of their products provided to Injured Infant when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or
- e. Representing that their cow's milk-based products were necessary to the growth and nutrition of premature infants on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent when they knew or should have known that their products were not necessary to achieve adequate growth; and/or
- f. Representing that their cow's milk-based products were necessary to the growth and nutrition of premature infants on the packaging and labeling of their products provided to Injured Infant when they knew or should have known that their products were not necessary to achieve adequate growth; and/or
- g. Representing that their cow's milk-based products were similar or equivalent to breast milk on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent; and/or

- h. Representing that their cow's milk-based products were similar or equivalent to breast milk on the packaging and labeling of their products provided to Injured Infant; and/or
- i. Representing that their cow's milk-based products could be fed with confidence to premature infants and/or that premature infants would be healthy regardless of whether they were fed their cow's milk-based products or breast milk on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent; and/or
- j. Representing that their cow's milk-based products could be fed with confidence to premature infants and/or that premature infants would be healthy regardless of whether they were fed their cow's milk-based products or breast milk on the packaging and labeling of their products provided to Injured Infant; and/or
- k. Representing that their cow's milk-based products have no serious side effects on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent when they knew or should have known the contrary to be true; and/or
- l. Representing that their cow's milk-based products have no serious side effects on the packaging and labeling of their products provided to Injured Infant when they knew or should have known the contrary to be true; and/or
- m. Representing that their cow's milk-based products were similar or equivalent to breast milk on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent when they knew or should have known the contrary to be true; and/or

- n. Representing that their cow's milk-based products were similar or equivalent to breast milk on the packaging and labeling of their products provided to Injured Infant when they knew or should have known the contrary to be true; and/or
- o. Representing that their cow's milk-based products were safe for premature infants on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent; and/or
- p. Representing that their cow's milk-based products were safe for premature infants on the packaging and labeling of their products provided to Injured Infant; and/or
- q. Representing that their cow's milk-based products were necessary for optimum growth on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent; and/or
- r. Representing that their cow's milk-based products were necessary for optimum growth on the packaging and labeling of their products provided to Injured Infant; and/or
- s. Representing that their products were based on up-to-date science, which made them safe for premature infants on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent; and/or
- t. Representing that their products were based on up-to-date science, which made them safe for premature infants on the packaging and labeling of their products provided to Injured Infant.

149. Abbott and Mead were negligent or careless in not determining those representations to be false.

150. The Defendant Manufacturers' misrepresentations induced, and were intended to induce, the Plaintiff Parent to allow their child to be fed Abbott's and Mead's infant products, in justifiable reliance on all the messaging they received about formula feeding, including, directly or indirectly, the Defendant Manufacturers' messaging. Had Abbott and Mead not committed these negligent misrepresentations, the Injured Infant would not have been exposed to their unreasonably dangerous cow's milk-based products.

151. As a direct and proximate result, Abbott's and Mead's products were fed to the Injured Infant, which caused and/or increased of their developing NEC and subsequent injuries.

152. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or

malicious conduct, as permitted by law;

- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT VI: FAILURE TO WARN
(Against Penn Medicine and Pennsylvania Hospital)**

153. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

154. Penn Medicine and Pennsylvania Hospital as purchaser, supplier, and/or distributor of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to purchase, supply, and distribute products that were free of unreasonable risk of harm when used in their intended manner and for their intended purpose, and/or to formulate, adopt, and enforce adequate rules and policies for the same.

155. At all times relevant to this action, the Injured Infant used the cow's milk-based products purchased, supplied, and/or distributed by Penn Medicine and Pennsylvania Hospital in their intended manner and for their intended purpose.

156. Penn Medicine and Pennsylvania Hospital employed or contracted with the healthcare professionals and medical staff at Pennsylvania Hospital, managing these individuals during their treatment of the Injured Infant.

157. Penn Medicine and Pennsylvania Hospital negligently, outrageously, and recklessly supplied and distributed the Defendant Manufacturers' milk-based infant feeding products to these healthcare professionals and medical staff for use on premature infants, including the Injured Infant.

158. Moreover, at all relevant times, Penn Medicine and Pennsylvania Hospital knowingly authorized the Defendant Manufacturers' sales representatives to market, advertise, distribute, and/or sell their products at Pennsylvania Hospital. The Defendant Manufacturers' sales representatives were encouraged to interact with Pennsylvania Hospital's healthcare professionals and medical staff. These interactions provided the Defendant Manufacturers' sales representatives an opportunity to co-opt Pennsylvania Hospital's healthcare professionals and medical staff into assisting with the marketing, distribution, and/or sale of the Defendant Manufacturers' unreasonably dangerous products to consumers, such as the Plaintiff Parent.

159. Penn Medicine and Pennsylvania also knowingly, and intentionally, allowed the Defendant Manufacturers' sales representatives to routinely misrepresent the risks and benefits of Defendants' products to Pennsylvania Hospital's healthcare professionals and medical staff, including the misrepresentation that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

160. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known at the time that they acquired, distributed, and supplied the Defendant Manufacturers' cow's milk-based infant products that these products significantly increased the risk of NEC, serious injury, and death.

161. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, outrageously, and recklessly, and breached its duty by:

- a. Failing to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in those babies; and/or
- b. Failing to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or

- c. Failing to warn or instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risk; and/or
- d. Failing to provide its healthcare professionals and medical staff with the well-researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or
- e. Failing to provide a warning in a method reasonably calculated/expected to reach the parents of newborns; and/or
- f. Failing to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products; and/or
- g. Failing to prevent the Defendant Manufacturers' sales representatives from misrepresenting to Pennsylvania Hospital's healthcare professionals and medical staff that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

162. Reasonable hospitals under the same or similar circumstances would have warned of the above risks, would have instructed their healthcare professionals and medical staff—as well as patients—on the safe use of the Defendant Manufacturers' products, and would have restricted the ability of the Defendant Manufacturers' sales representatives to market the Defendant Manufacturers' unreasonably dangerous products without adequate warning.

163. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that its medical professionals and the parents of premature infants, including the Plaintiff Parent, would not have realized the risks associated with feeding cow's milk-based formula to premature infants.

164. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its duty to warn its medical providers and patients about the Defendant Manufacturers' unreasonably dangerous products, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

165. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital's failure to warn of the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

166. As a further direct and proximate result of Penn Medicine and Pennsylvania Hospital's failure to warn of the Defendant Manufacturers' unreasonably dangerous products, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against Penn Medicine and Pennsylvania Hospital, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of Penn Medicine's conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit

resulting from Penn Medicine and Pennsylvania Hospital's oppressive, outrageous, reckless, and/or malicious conduct, as permitted by law;

- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT VII: CORPORATE LIABILITY OF HEALTH-CARE PROVIDER
(Against Penn Medicine and Pennsylvania Hospital)**

167. Plaintiff incorporates by references each of the preceding paragraphs as if fully set forth herein.

168. At all relevant times, Penn Medicine and Pennsylvania Hospital owed a duty of care to the Injured Infant to ensure their safety and well-being while the Injured Infant was under the care of Pennsylvania Hospital staff. Specifically, Penn Medicine and Pennsylvania Hospital had a duty to the Injured Infant to formulate, adopt, and enforce adequate rules and policies to ensure quality care for the Injured Infant. Further, Penn Medicine and Pennsylvania Hospital owed a duty to the Injured Infant to oversee its healthcare professionals and medical staff that provided patient care to the Injured Infant.

169. Penn Medicine and Pennsylvania Hospital owed a duty to its patients, and the Injured Infant in particular, to formulate, adopt, and enforce adequate rules and policies for the purchase, supply, distribution, and use of products that were free of unreasonable risk of harm when used in their intended manner and for their intended purpose and ensured quality care for the Injured Infant.

170. At all times relevant to this action, the Injured Infant used the cow's milk-based products purchased, supplied, and/or distributed by Penn Medicine and Pennsylvania Hospital in their intended manner and for their intended purpose.

171. Moreover, at all relevant times, Penn Medicine and Pennsylvania Hospital knowingly authorized the Defendant Manufacturers' sales representatives to market, advertise, distribute, and/or sell their products at Pennsylvania Hospital. The Defendant Manufacturers' sales representatives were encouraged to interact with Pennsylvania Hospital's healthcare professionals and medical staff. These interactions provided the Defendant Manufacturers' sales representatives an opportunity to co-opt Pennsylvania Hospital's healthcare professionals and medical staff into assisting with the marketing, distribution, and/or sale of the Defendant Manufacturers' unreasonably dangerous products.

172. Penn Medicine and Pennsylvania Hospital also knowingly allowed the Defendant Manufacturers' sales representatives to routinely misrepresent the risks and benefits of Defendants' products to Pennsylvania Hospital's healthcare professionals and medical staff, including the misrepresentation that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

173. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known at the time that it formulated, adopted, and enforced its rules for the acquisition, distribution, and supply of the Defendant Manufacturers' cow's milk-based infant products, including the access afforded the Defendant Manufacturer's sales representatives, that these products significantly increased the risk of NEC, serious injury, and death for premature infants.

174. Since prior to 2000, Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that premature babies are increased risk for NEC.

175. Since prior to 2000, Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that NEC increases the risk of permanent injury and death.

176. Since 2000, Penn Medicine and Pennsylvania Hospital knew or reasonably should have

known prior to that human milk (mother's milk) was safest and best for premature infants.

177. Since 2000, Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that human milk (mother's milk) decreased the risk of NEC, serious injury, and death for premature infants.

178. By no later than 2012, Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that donor human milk decreased the risk of NEC, serious injury, and death for premature infants.

179. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that its medical professionals and the parents of premature infants, including the Plaintiff Parent, would not have realized the risks associated with feeding cow's milk-based formula to premature infants.

180. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, outrageously, and recklessly, and breached its duty by:

- a. Failing to formulate, adopt, and enforce adequate rules and policies that would have required human milk (mother's milk and/or donor milk) to be recommended to premature babies; and/or
- b. Failing to formulate, adopt, and enforce adequate rules and policies that would have restricted or prevented the use of cow's milk-based products for feeding premature babies; and/or
- c. Failing to formulate, adopt, and enforce adequate rules and policies that informed the Plaintiff Parent that human milk (mother's milk and/or donor milk) significantly decrease the risk of NEC, severe injury, and death in premature babies, like the Injured Infant; and/or
- d. Failing to formulate, adopt, and enforce adequate rules and policies that warned the

Plaintiff Parent that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in premature babies, like the Injured Infant; and/or

- e. Failing to formulate, adopt, and enforce adequate rules and policies that discussed the risks of cow's milk-based products significantly increasing the risk of NEC, severe injury, and death in premature babies, like the Injured Infant; and/or
- f. Failing to formulate, adopt, and enforce adequate rules and policies that warned its healthcare professionals and medical staff that cow's milk-based products are unsafe and/or contraindicated for premature babies like the Injured Infant; and/or
- g. Failing to formulate, adopt, and enforce adequate rules and policies to instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risk; and/or
- h. Failing to formulate, adopt, and enforce adequate rules and policies to provide its healthcare professionals and medical staff with the well-researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or
- i. Failing to formulate, adopt, and enforce adequate rules and policies to ensure a warning in a method reasonably calculated/expected to reach the parents of premature newborns, like the Plaintiff Parent; and/or
- j. Failing to formulate, adopt, and enforce adequate rules and policies to prevent the Defendant Manufacturers' sales representative from misrepresenting to Pennsylvania Hospital's healthcare professionals and medical staff that premature

babies would not grow adequately with human milk and human milk products and/or that use of donor milk was not advised for premature infants; and/or

- k. Failing to establish a donor milk program that was sufficient to meet the needs of the premature babies, like the Injured Infant.
- l. Failing to formulate, adopt, and enforce adequate rules and policies regarding the feeding of premature infants leaving it to the discretion of the medical team and parent without a discussion of risks and benefits.
- m. Allowing parental preference to be the standard for feeding premature infants;
- n. Failing to follow the American Academy of Pediatrics recommendations relating to feeding premature infants;
- o. Failing to follow the American Academy of Pediatrics recommendations to use donor milk if mother's milk was unavailable instead of cow's milk-based products;
- p. Failing to recommend donor milk if mother's milk was unavailable by no later than 2012; and
- q. Failing to transfer to a hospital by no later than 2012 where donor milk was available if there was no donor milk available.

181. A reasonable hospital under the same or similar circumstances would have formulated, adopted, and enforced adequate policies, and rules to restrict the feeding of cow's milk-based products to premature babies, including developing an adequate donor milk program, instructing its healthcare professionals and medical staff on the safe use of Defendants Manufacturers' cow's milk-based products, and restricting the marketing of the Defendant Manufacturers' unreasonably dangerous products to its healthcare professionals, medical staff, and parents of premature infants under its care.

182. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its duty to formulate, adopt, and enforce adequate rules and policies to ensure the quality care of its patients, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

183. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital failure to formulate and enforce adequate policies and rules related to the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

184. As a further direct and proximate result of Penn Medicine and Pennsylvania Hospital negligent, reckless, and outrageous conduct the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

185. In the alternative, Penn Medicine and Pennsylvania Hospital owed a duty to its patients, and the Injured Infant in particular, to oversee the practicing healthcare professionals and medical staff that provided the products at issue to infants under Pennsylvania Hospital's care, including the Injured Infant.

186. Penn Medicine and Pennsylvania Hospital employed or contracted with the healthcare professionals and medical staff at Pennsylvania Hospital and was responsible for overseeing those individuals during their treatment of the Injured Infant.

187. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, recklessly, and outrageously breached its duty by:

- a. Failing to oversee its healthcare professionals and medical staff on their use of

cow's milk-based products for feeding premature babies; and/or

- b. Failing to warn or instruct its healthcare professionals and medical staff that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in those babies; and/or
- c. Failing to warn or instruct its healthcare professionals and medical staff that cow's milk-based products are unsafe and/or contraindicated for premature babies like the Injured Infant; and/or
- d. Failing to oversee its healthcare professionals and medical staff to restrict their feeding of cow's milk-based products to premature babies; and/or
- e. Failing to warn or instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risk; and/or
- f. Failing to provide its healthcare professionals and medical staff with the well-researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or
- g. Failing to provide its healthcare professionals and medical staff with warnings about the dangers of the Defendants' Manufacturers products in a method reasonably calculated/expected to reach the parents of newborns; and/or
- h. Failing to provide statistical evidence to its healthcare professionals and medical staff showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products; and/or
- i. Failing to oversee its healthcare professionals and medical staff to ensure that the

Defendant Manufacturers' sales representatives' misrepresentations that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants had not influenced the use and/or misuse of the Defendant Manufacturers' products.

188. A reasonable hospital under the same or similar circumstances would have warned of the above risks, would have instructed its healthcare professionals and medical staff on the safe use of the Defendant Manufacturers' products, and would have restricted the ability of the Defendant Manufacturers' sales representatives to market the Defendant Manufacturers' unreasonably dangerous products without adequate warning.

189. A reasonable hospital under the same or similar circumstances would have overseen and managed its healthcare professionals and medical staff to ensure that they received proper training and updating on the risks associated with feeding cow's milk-based formula to premature infants.

190. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its duty to oversee its healthcare professionals and medical staff who provide patient care, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

191. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital's failure to oversee its healthcare professionals and medical staff on the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

192. As a further direct and proximate result of Penn Medicine and Pennsylvania Hospital's negligent and reckless conduct, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's

injuries.

WHEREFORE, Plaintiff demands judgment against Penn Medicine and Pennsylvania Hospital, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of Penn Medicine and Pennsylvania Hospital's conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from Penn Medicine's oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

DEMAND FOR JURY TRIAL

193. Plaintiff hereby demands a jury trial for all claims triable.

Dated: 7/16/2024

Respectfully submitted,

KLINE & SPECTER, P.C.

By: /s/ Tobias L. Millrood
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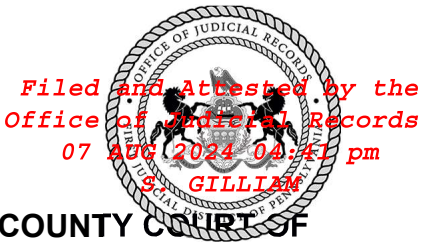
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EXHIBIT A-66



**ALICE STILLS, on her own behalf and
as Parent and Natural Guardian of
M.E., a Minor**

**Plaintiff,
v.**

**MEAD JOHNSON & COMPANY, LLC,
et al.,**

Defendants.

**PHILADELPHIA COUNTY COURT OF
COMMON PLEAS**

**MARCH TERM, 2022
No. 02617**

ORDER

AND NOW, this day of 2024, upon consideration of the Preliminary Objections of Defendants Mead Johnson & Company, LLC and Mead Johnson Nutrition Company (collectively, "Mead Johnson" or "Moving Defendants") to Plaintiffs' Second Amended Complaint, and any Response thereto, it is hereby **ORDERED** that the Preliminary Objections are **SUSTAINED**. It is further **ORDERED** that all claims against Defendants Mead Johnson & Company, LLC and Mead Johnson Nutrition Company are hereby **DISMISSED** with prejudice.

BY THE COURT:

J.

**ALICE STILLIS, on her own behalf and
as Parent and Natural Guardian of
M.E., a Minor**

**Plaintiff,
v.**

**MEAD JOHNSON & COMPANY, LLC,
et al.,**

Defendants.

**PHILADELPHIA COUNTY COURT OF
COMMON PLEAS**

**MARCH TERM, 2022
No. 02617**

ORDER

AND NOW, this day of 2024, upon consideration of the Preliminary Objections of Defendants Mead Johnson & Company, LLC and Mead Johnson Nutrition Company (collectively, “Mead Johnson” or “Moving Defendants”) to Plaintiffs’ Second Amended Complaint, and any Response thereto, it is hereby **ORDERED** that the Preliminary Objections are **SUSTAINED**. It is further **ORDERED** that:

1. Count I of Plaintiffs’ Second Amended Complaint is **DISMISSED** with prejudice;
2. Count II of Plaintiffs’ Second Amended Complaint is **DISMISSED** with prejudice;
3. Count III of Plaintiffs’ Second Amended Complaint is **DISMISSED** with prejudice;
4. Count IV of Plaintiffs’ Second Amended Complaint is **DISMISSED** with prejudice;
5. Count V of Plaintiffs’ Second Amended Complaint is **DISMISSED** with prejudice;
6. Plaintiffs’ Second Amended Complaint is **STRICKEN** for lack of specificity;
7. Plaintiffs’ claims for punitive damages as to Defendants Mead Johnson & Company, LLC and Mead Johnson Nutrition Company are **DISMISSED** with prejudice, along with all allegations of oppressive, reckless, malicious and/or fraudulent conduct;
8. Plaintiff Alice Stills claims in her own right are **DISMISSED** with prejudice; and

9. Plaintiffs' Second Amended Complaint is **STRICKEN** for lack of an appropriate verification.

BY THE COURT:

J.

NOTICE TO PLEAD:

To Plaintiff: You are hereby notified to file a written response to the enclosed Preliminary Objections within twenty (20) days from service hereof or a judgement may be entered against you.

/s/ Kenneth A. Murphy
Attorney for Defendants, Mead Johnson & Company, LLC and Mead Johnson Nutrition Company

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**ALICE STILLS, on her own behalf and
as Parent and Natural Guardian of
M.E., a Minor**

**Plaintiff,
v.**

**MEAD JOHNSON & COMPANY, LLC,
et al.,**

Defendants.

**PHILADELPHIA COUNTY COURT OF
COMMON PLEAS**

**MARCH TERM, 2022
No. 02617**

**PRELIMINARY OBJECTIONS OF DEFENDANTS MEAD JOHNSON & COMPANY,
LLC AND MEAD JOHNSON NUTRITION COMPANY TO PLAINTIFFS' SECOND
AMENDED COMPLAINT**

Defendants Mead Johnson & Company, LLC and Mead Johnson Nutrition Company (hereinafter “Moving Defendants” or “Mead Johnson”) hereby preliminarily object to Plaintiffs’ Second Amended Complaint (hereinafter “Amended Complaint” or “Complaint”), and, in support thereof, aver as follows:

I. INTRODUCTION

1. This case against Mead Johnson involves speculative and unsupported allegations by Plaintiffs that the minor Plaintiff, M.E., developed a condition known as necrotizing enterocolitis (“NEC”) following his alleged ingestion of “Similac and/or Enfamil” cow’s milk-based infant human milk fortifier manufactured and sold by Mead Johnson and/or defendant Abbott Laboratories (“Abbott”). Plaintiffs have had more than two years to correct fatal pleading deficiencies. See 7/25/2023 Order Setting Amended Complaint Deadlines and 5/20/2024 Order Setting Amended Complaint Deadlines. Despite these two years, and two rounds of preliminary objections from Defendants detailing the fatal pleading deficiencies, Plaintiffs still have not identified any Mead Johnson product that M.E. purportedly ingested. Further, *the entirety* of Plaintiffs’ claims rest on their unsubstantiated conclusion that the formula consumed by M.E. is an unreasonably dangerous product.

2. Plaintiffs acknowledge that premature infants such as M.E. have an inherently high risk of developing NEC. See Second Amended Complaint, attached as Exhibit “A,” at ¶ 22 (“Preterm and low-birth-weight infants are especially susceptible to NEC because of their underdeveloped digestive systems.”). Not only is the Second

Amended Complaint entirely devoid of any claims regarding specific Mead Johnson products fed to M.E., the Complaint also lacks factual support for Plaintiffs' claim that any Mead Johnson's product caused M.E. to develop NEC. Plaintiffs allege only that M.E. was born on a certain date; *may* have been provided one of Defendants' infant formula products; and, at some point, developed NEC. Plaintiffs nowhere allege how cow's milk purportedly *causes* NEC, or how the facts of M.E.'s case relate to the scientific evidence Plaintiffs cite. Pennsylvania's procedural rules do not allow for such gaps in logic and omissions of material facts in a complaint. *Northern Forests II, Inc. v. Keta Realty Co.*, 130 A.3d 19, 35 (Pa. Super. 2015) (requiring plaintiffs to aver sufficient facts, together with the documents and exhibits attached thereto, to make out a prima facie case as to all elements of the cause of action, in order to survive preliminary objections). Accordingly, Plaintiffs' Second Amended Complaint should be dismissed.

3. Plaintiffs instituted this action via the filing of a Complaint on March 24, 2022, against Moving Defendants as well as Co-Defendants Abbott and The Pennsylvania Hospital of the University of Pennsylvania and The Trustees of the University of Pennsylvania ("HUP"). Plaintiffs subsequently served a Second Amended Complaint on July 18, 2024. See Plaintiffs' Second Amended Complaint, attached as Exhibit "A."

4. Plaintiffs have filed nearly 30 essentially identical lawsuits against Moving Defendants, Abbott, HUP, and other hospitals in Philadelphia based on claims relating to alleged ingestion of cow's milk-based infant formula by premature infants following their birth.

5. Plaintiffs allege that, “upon information and belief,” the Plaintiff-minors, including M.E., developed NEC, a gastrointestinal disorder that occurs in premature infants. See Ex. “A,” at ¶ 13. Plaintiffs allege that premature infants fed with their mother’s breast milk or donor breast milk are at decreased risk of developing NEC, as compared with infants given cow’s milk-based infant formula.

6. In addition to asserting product liability claims against Moving Defendants and Abbott, as the infant formula manufacturers, Plaintiffs have brought claims against The Pennsylvania Hospital of the University of Pennsylvania and The Trustees of the University of Pennsylvania alleging liability on theories of failure to warn and corporate liability.

7. The factual background regarding the Plaintiff-minor’s birth, diagnosis and injuries are limited to ten (10) paragraphs in the Complaint.

8. Plaintiffs aver that M.E. was born prematurely on September 28, 2007, and that at birth his gestational age and weight were approximately 28 weeks and 622 grams, respectively. See Ex. “A,” at ¶¶ 11-12.

9. Plaintiffs allege that “Upon information and belief, M.E. was fed Similac and/or Enfamil cow’s milk-based products”. *Id.* at ¶ 13.

10. Plaintiffs further aver “On November 2, 2007 M.E. was diagnosed in the Pennsylvania Hospital NIC-U with stage II-B Medical NEC.” *Id.* at ¶ 16.

11. The Mead Johnson Defendants Preliminarily Object to Plaintiffs’ Second Amended Complaint for the reasons stated below and as more fully set forth in the accompanying Memorandum of Law, which is incorporated herein by reference.

II. ARGUMENT

A. DEMURRER FOR FAILURE TO STATE A CLAIM AS TO COUNTS I, II, III, IV, & V

12. Plaintiffs allege in Counts I and II of the Second Amended Complaint that Moving Defendants, “as the manufacturers and/or sellers of the products at issue in this litigation,” owed Plaintiffs and the public a duty to manufacture, sell, and distribute their products in a manner that was not unreasonably dangerous and to warn of unreasonable risk of harm posed by their products.

13. Plaintiffs allege in Count III (Negligence) of the Complaint that Moving Defendants, “as the manufacturers and/or sellers of the products at issue in this litigation” owed Plaintiffs and the public a duty to exercise reasonable care to design, test, manufacture, inspect, and distribute products that were free of unreasonable risk of harm.

14. Plaintiffs allege in Count IV (Intentional Misrepresentation) and Count V (Negligent Misrepresentation) of the Complaint that Moving Defendants, “as the manufacturers and/or sellers of the products at issue in this litigation” owed Plaintiffs and the public a duty to provide truthful, accurate, fulsome information about their cow’s milk-based products.

15. Counts I, II, III, IV, and V are based upon Plaintiffs’ theory against Moving Defendants that Moving Defendants’ cow’s milk-based products are unreasonably dangerous, and for strict liability purposes in Counts I & II, defective.

16. In support of their theories and claims, Plaintiff merely alleges that studies have “confirmed that cow’s milk-based feeding products cause NEC,” but does not cite or attach any studies. See Exhibit “A,” ¶¶ 22.

17. Taking these facts as pleaded by Plaintiffs as true, Plaintiffs have failed to state a claim for defective design and failed to state a claim for failure-to-warn, due to an absence of proof of that the products are indeed unreasonably dangerous.

18. As is discussed in detail in the accompanying Memorandum of Law, infant formulas are regulated by the United States Food and Drug Administration (“FDA”) and are required to include specified vitamins and nutrients, including infant formulas intended for low birth weight infants.

19. The FDA does not restrict the use of cow’s milk-based infant formula for premature or low birth weight infants. Thus, Plaintiffs’ contention that cow’s milk-based infant formula should never be given to premature infants is not supported by the FDA.

20. “The law governing strict products liability actions in Pennsylvania has been developed based upon the principles outlined in Section 402A of the Second Restatement of Torts.” *High v. Pennsy Supply, Inc.*, 154 A.3d 341 (Pa. Super. 2017). Section 402(A) provides:

- (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
 - (a) the seller is engaged in the business of selling such a product, and
 - (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
- (2) The rule stated in Subsection (1) applies although
 - (a) the seller has exercised all possible care in the preparation and sale of his product, and

- (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

Restatement (Second) of Torts § 402(A).

21. To survive preliminary objections, Plaintiffs must aver sufficient facts, together with the documents and exhibits attached thereto, to make out a *prima facie* case as to all elements of the cause of action. *Northern Forests II, Inc. v. Keta Realty Co.*, 130 A.3d 19, 35 (Pa. Super. 2015).

22. “The threshold inquiry in all products liability cases is whether there is a defect which rendered the product unreasonably dangerous.” *Weiner v. American Honda Motor Co., Inc.*, 718 A.2d 305, 307 (Pa. Super. 1998). “A product is defective when it is not safe for its intended use, *i.e.*, the product left the supplier's control lacking any element necessary to make it safe for its intended use.” *Id.* at 308. Whether a product is “unreasonably dangerous” is a question of law. *Id.*

23. Based on the foregoing, the threshold Plaintiffs must cross as to Counts I, II, III, IV, and V, is that Plaintiffs must aver sufficient facts demonstrating the Moving Defendants’ products are unreasonably dangerous for their intended use, triggering the duties set forth in Plaintiffs’ Complaint at Counts I, II, III, IV, and V.

24. Although Plaintiff alludes to research studies relating to the purported risks of cow’s milk-based products in premature infants, those studies demonstrate only, assuming the facts as true as stated by Plaintiffs, that premature infants are at high risk of NEC, and that feeding such infants with breast milk may be better at reducing the risk of NEC than cow’s milk-based alternatives. See Exhibit “A,” ¶¶ 21-22.

25. At the outset, Plaintiffs appropriately acknowledge that “[p]reterm and low-birth-weight infants are *especially susceptible* to NEC.” See Exhibit “A” at ¶ 22 (emphasis added).

26. In support of their theories and claims, Plaintiffs offer only vague references to unidentified “[e]xtensive scientific research, including numerous randomized controlled trials” that purportedly prove Moving Defendants’ cow’s milk-based products cause NEC in preterm and low-birth-weight infants. See *id.* Plaintiffs neither cite specifically to any randomized trial or consensus statement, nor do they explain the purported method of action by which cow’s milk-based formula products allegedly cause NEC.

27. In their original complaint, Plaintiffs did specifically cite five studies comparing cow’s milk-based products to breast milk, Compl. at ¶¶ 17, 18, 19, 22, and 23, a Surgeon General report on the subject, *id.* at ¶ 20, and a statement by the American Academy of Pediatrics. *Id.* at ¶ 21. Those studies, the report, and the statement purportedly reference higher rates of NEC in preterm and low birth weight infants fed cow’s milk-based diets than those fed breast milk. They do not establish or prove causation. At best, they provide support for what neonatologists around the country already know: “Using human breast milk to feed preterm infants may reduce the risk of NEC, but it does not eliminate this risk.” News Release, Am. Academy of Pediatrics, *AAP Statement In Response to NEC Lawsuits*.¹

¹ On July 27, 2024, the American Academy of Pediatrics issued a news release that further explained:

“Part of what is so challenging about NEC is that the causes are multifaceted and not completely understood. Our science does not tell us exactly how to prevent it. . . . Special formulas designed for preterm infants provide an essential source of nutrition. Using human breast milk to feed preterm infants may reduce the risk of

28. Given that Plaintiffs have offered nothing but the bald assertion that there is “extensive scientific research” that Moving Defendants’ products cause NEC, Plaintiffs have failed to adequately allege that the products are unreasonably dangerous. Accordingly, they have failed to state claims for defective design and failure-to-warn. Counts I through V should be stricken.

B. DEMURRER FOR FAILURE TO STATE A CLAIM AS TO COUNTS IV & V

29. Plaintiffs’ claims for intentional and negligent misrepresentation (Counts IV and V) fail because Plaintiffs once again fail to plead their allegations with particularity, as required by Pa. R. Civ. P. 1019(b). Specifically, Plaintiffs do not allege that they received and relied upon any particular false representation from Moving Defendants. *See Bortz v. Noon*, 729 A.2d 555, 560 (Pa. 1999) (setting forth the elements of intentional and negligent misrepresentation and noting that both require a false representation upon which the plaintiff ultimately relied). Plaintiffs cannot maintain misrepresentation claims because they fail to allege that they received any specific representation from Moving Defendants on which they relied. In fact, as they have not even alleged that M.E. received a Mead Johnson product, they cannot claim that misrepresentations by Mead Johnson caused reliance or their purported injury.

NEC, but it does not eliminate this risk. Donated human milk is also used when the mother’s own milk is not available in sufficient quantities, but there is not enough donated human milk to be used as the only source of nutrition for these infants. Providing special formula is a routine and necessary part of care of these preterm infants.”

News Release, Am. Acad. of Pediatrics, AAP Statement in Response to NEC Lawsuit Verdicts (July 27, 2024), https://www.aap.org/en/news-room/news-releases/aap/2024/aap-statement-in-response-to-nec-lawsuit-verdicts/?_ga=2.95418713.417221795.1722442775-1510920779.1722442775.

30. The elements of a claim for negligent misrepresentation are: “(1) a misrepresentation of a material fact; (2) made under circumstances in which the misrepresenter ought to have known its falsity; (3) with an intent to induce another to act on it; and (4) which results in injury to a party acting in justifiable reliance on the misrepresentation.” *Bilt-Rite Contractors v. Architectural Studio*, 866 A.2d 270, 277 (Pa. 2005) (quoting *Bortz v. Noon*, 556 Pa. 489, 729 A.2d 555, 561 (Pa. 1999)). Negligent misrepresentation differs from intentional misrepresentation “in that the misrepresentation must concern a material fact and the speaker need not know his or her words are untrue, but must have failed to make a reasonable investigation of the truth of these words.” *Bortz*, 729 A.2d at 561.

31. The elements of an intentional misrepresentation claim require: “(1) A representation; (2) which is material to the transaction at hand; (3) made falsely, with knowledge of its falsity or recklessness as to whether it is true or false; (4) with the intent of misleading another into relying on it; (5) justifiable reliance on the misrepresentation; and (6) the resulting injury was proximately caused by the reliance.” *Bortz*, 729 A.2d at 499 (citing *Gibbs v. Ernst*, 647 A.2d 882, 889 (1994), citing, Restatement (Second) of Torts § 525 (1977)).

32. Here, Plaintiffs’ claims fail to allege that they received any specific representation from Moving Defendants, intentional or otherwise. Plaintiffs further fail to allege that they relied on a specific representation of the Moving Defendants.

33. Because of these omissions from Plaintiffs’ Complaint, Plaintiffs have failed to articulate a viable claim for intentional and negligent misrepresentation. See, e.g., *Cruz v. Roberts*, No. CI-04-01947, 2005 Pa. Dist. & Cnty. Dec. LEXIS 186, 70 Pa. D. & C.4th

225 (Pa. CCP Jan. 26, 2005) (dismissing negligent and intentional misrepresentation claims for insufficient pleading); see also *Kepner v. Tine*, No. 835 EDA 2015, 2015 Pa. Super. Unpub. LEXIS 4257 (Pa. Super. Nov. 25, 2015) (dismissing fraudulent misrepresentation claim for failure to plead a particular misrepresentation).

34. Thus, Plaintiffs' intentional and negligent misrepresentation claims against Moving Defendants must be dismissed.

C. MOTION TO STRIKE PLAINTIFFS' COMPLAINT FOR INSUFFICIENT SPECIFICITY AS TO THE FACTS AND ALLEGED INJURIES

35. Pursuant to Pa.R.C.P. 1028(a)(3), a party may file preliminary objections in the nature of a motion to strike for insufficient specificity in a pleading. Plaintiffs' failure to specify the specific Mead Johnson products M.E. received and the exact nature of his ongoing injuries serves as an alternative ground on which all of their claims should be stricken.

36. A plaintiff's Complaint is required to provide a defendant with notice of what the plaintiff's claims are and the grounds upon which they rest, and the Complaint must also formulate the issues by summarizing the facts essential to support the claims. *Alpha Tau Omega Fraternity v. The University of Pennsylvania*, 464 A.2d 1349, 1352 (Pa. Super. 1983) (citations omitted).

37. Pennsylvania Rule of Civil Procedure 1019(a) provides that "the material facts on which a cause of action or defense is based shall be stated in a concise and summary form." Pa.R.C.P. 1019(a). As the Superior Court has noted,

Rule 1019(a) requires fact pleading. The purpose of 1019(a) is to require the pleader to disclose the material facts sufficient to enable the adverse party to prepare his case. **A complaint therefore must do more than give the defendant fair notice of what the plaintiff's claim is and**

the grounds upon which it rests. It should formulate the issues by fully summarizing the material facts. Material facts are ultimate facts, i.e., those facts essential to support the claim. Evidence from which such facts may be inferred not only need not but should not be alleged. Allegations will withstand challenge under 1019(a) if (1) they contain averments of all of the facts a plaintiff will eventually have to prove in order to recover, and (2) they are sufficiently specific so as to enable defendant to prepare his defense.

Baker v. Rangos, 324 A.2d 498, 505-506 (Pa. Super. 1974) (citations and internal quotations omitted) (emphasis added).

38. Further, it is well established that, with regard to the description of injuries sustained by a plaintiff, the Complaint must be stated with sufficient particularity to put the defendant on notice of evidence that may be produced at trial. *Kelly v. Martino*, 99 A.2d 901 (Pa. 1953). **A plaintiff's Complaint must set forth the extent, nature, location and duration of the injuries suffered, and injuries that are permanent should be stated specifically.** *Miller v. Perrige*, 71 Pa. D. & C.2d 476, 479–80 (Pa. Com. Pl. 1975). *See also Kopan v. Hawk*, 14 Pa. D. & C.2d 713, 714 (Pa. Com. Pl. 1958) (“A catchall averment of “other injuries” is nothing more than a generalized averment under which any injuries whatever could be proved at the trial. Defendant would have no knowledge in advance of the trial of what they are.”)

39. Plaintiffs' Second Amended Complaint is facially deficient with regard to the specificity of the allegations of the relevant facts and injuries at issue in this case.²

² Access to the relevant medical records **before** filing suit would have allowed Plaintiffs to comport themselves consistently with Rule 1019(a). Given that minor plaintiff's purported claims are tolled until age of majority, no good reason exists for Plaintiffs' failure to support their complaint with required facts.

40. Plaintiffs' description of the material facts relating to the minor's care and treatment, diagnosis and injuries is limited to ten paragraphs, which are utterly insufficient to enable defendants to prepare their defenses. See Ex. "A," at ¶¶ 11-20.

41. Plaintiffs' allegation that "upon information and belief," the minor was fed Similac and/or Enfamil shortly after his birth (*Id.* at ¶ 13) does not comply with the fact-pleading requirements of Rule 1019(a), since such allegations do not provide Moving Defendants with appropriate notice of the facts as to whether the minor actually ingested cow's milk-based products.

42. Further, Plaintiffs have failed to identify which of the numerous products sold by Abbott and Mead Johnson under the Similac and Enfamil brand names were ingested by the minor. *Id.* at ¶¶ 62-63.

43. Plaintiffs' Second Amended Complaint further fails to provide a description of the material facts as to the period of time in which such products were ingested, when the minor was allegedly diagnosed with NEC and what treatment was provided for that condition.

44. The Second Amended Complaint further fails to state the nature of the injuries and "long-term health issues" that are alleged to have resulted from the diagnosis of NEC.

45. Plaintiffs' damages claim is not stated with particularity, is amorphous, vague, and open-ended. Pursuant to Pennsylvania pleading requirements, Moving Defendants should not be compelled to defend a claim for which the statement of injury is unspecified and subject to change.

46. These omissions are fatal defects in Plaintiffs' Second Amended Complaint. Therefore, Plaintiffs' Second Amended Complaint should be stricken in its entirety.

D. MOTION TO STRIKE PLAINTIFFS' CLAIMS FOR PUNITIVE DAMAGES

47. In the *Ad Damnum* clauses of Counts I, II, III, IV, and V of the Complaint, Plaintiffs make baseless accusations that Moving Defendants engaged in oppressive, reckless, malicious and/or fraudulent conduct that allegedly justify an award of punitive damages. See Exhibit "A," pp. 28, 31, 34, and 37.

48. However, the Second Amended Complaint contains no specific allegations of conduct that would permit recovery of punitive damages as to Moving Defendants.

49. Plaintiffs' allegations of oppressive, malicious and similar conduct must be rejected as mere boilerplate. As discussed above, the FDA specifically approves the use of infant formula in care of low birth weight infants, with no restriction as to the use of cow's milk-based products for such infants.

50. Indeed, the fact that Plaintiffs have filed numerous lawsuits against at least four other hospitals in Philadelphia based on identical claims belies the contention that Moving Defendants engaged in outrageous or malicious conduct in allegedly feeding the Plaintiff-minor with cow's milk-based infant formula.

51. Absent specific factual allegations to justify the claim that the use of infant formula in M.E.'s case was extreme and outrageous, there is no basis for an award of punitive damages in this case.

52. Merely contending that punitive damages should be awarded with no supporting factual justification requires dismissal of this claim.

53. Since the purpose of punitive damages is not compensation of a plaintiff but punishment of the defendant and deterrence, punitive damages can be awarded only for conduct involving some element of outrage. *Hutchinson v. Luddy*, 582 Pa. 114, 870 A.2d 766 (2005). For that reason, Pennsylvania Supreme Court decisions establish that “punitive damages are an ‘extreme remedy’ available in only the most exceptional matters.” *Wagner v. Onofrey*, 2006 Pa. Dist. & Cnty. Dec. LEXIS 333, *11 (Pa. Com. Pl. 2006) (citing *Phillips v. Cricket Lighters*, 584 Pa. 179, 188, 883 A.2d 439, 445 (2005)). “In fact, punitive damages are specifically designed to heap an additional punishment on a defendant who is found to have acted in a fashion which is particularly egregious.” *Wagner* at *12.

54. Punitive damages may not be awarded for misconduct that constitutes ordinary negligence such as inadvertence, mistake and errors of judgment. *Martin v. Johns-Manville Corp.*, 494 A.2d 1088, 1097 (Pa. 1985); *McDaniel v. Merck, Sharp & Dohme*, 533 A.2d 436, 437 (Pa. Super. 1987). An award of punitive damages must be supported by evidence of conduct more serious than the mere commission of the underlying tort. *Allstate Ins. Co. v. A.M. Pugh Assoc., Inc.*, 604 F. Supp. 85, 99 (M.D. Pa. 1984).

55. The Supreme Court has made clear that when assessing the propriety of the imposition of punitive damages, “the state of mind of the actor is vital. The act or failure to act, must be intentional, reckless or malicious.” *Hutchinson, supra* at 770. An appreciation of the risk is a necessary element of the mental state required for the imposition of punitive damages. *Id.* at 772.

56. Thus, “a punitive damages claim must be supported by evidence sufficient to establish that (1) a defendant had a subjective appreciation of the risk of harm to which the plaintiff was exposed and that (2) he acted, or failed to act, as the case may be, in conscious disregard of that risk.” *Id.*

57. Where the facts as averred show nothing more than negligence, a lapse in judgment, or mere inadvertence, courts in Pennsylvania have dismissed pleas and claims for punitive damages, often at the pleadings stage of litigation and even if the complaint alleged severe injuries or death. *See, e.g., Brownawell v. Bryan*, 40 Pa. D. & C.3d 604, 606 (Pa. Com. Pl. 1985) (dismissing punitive damages claim where a plaintiff alleged that a physician negligently performed a spinal fusion surgery that left the plaintiff with severe neurological defects, and noting that “**the mere pleading of outrageous conduct** does not, of course, satisfy the requirement stating facts which, if proven, would form a basis for a jury concluding that the conduct was such that an award of punitive damages was warranted.”) (emphasis added); *Wagner, supra* at *11 (contentions that physician failed to prescribe antibiotics, order certain tests or request an infectious disease consult constituted “nothing more than ordinary negligence and are insufficient to support an award of punitive damages.”); *McCardle v. Aldinger*, 5 Pa. D. & C.4th 421, 428 (Pa. Com. Pl. 1996) (sustaining preliminary objections and dismissing claim for punitive damages where the plaintiff alleged negligence in the prenatal care of her child that led to the child was stillborn and holding that “[i]t is not the outcome of the alleged negligence that is of consideration, but rather the alleged conduct of defendants that is at issue.”); *Flurer v. Pocono Medical Ctr.*, 15 Pa. D. & C.4th 645, 670 (Pa. Com. Pl. 1992) (sustaining preliminary objections and finding that plaintiffs were not “capable of pleading the

requisite behavior” for an award of punitive damages where a hospital allegedly failed to properly utilize a fetal monitor on a pregnant woman who was involved in a serious car accident and thereafter delivered a stillborn child).

58. Conversely, punitive damages have been reserved for those situations that are truly egregious and utterly outrageous, and typically involve aggravating or other factors that evince a particularly reckless mind or evil motive. *See, e.g., Medvecz v. Choi*, 569 F.2d 1221, 1227-30 (3rd Cir. 1987) (anesthesiologist who abandoned patient on operating room table and left room for a lunch break without securing a suitable replacement could be liable for punitive damages to patient who suffered irreversible paralysis from anesthesia complication that developed during his absence); *Hoffman v. Memorial Osteopathic Hospital*, 492 A.2d 1382, 386-87 (Pa. Super. 1985) (evidence that emergency room physician allowed Guillain-Barre Syndrome patient suffering from neurological paralysis to remain crying and immobile on floor for two hours as physician repeatedly stepped over patient was sufficient to support punitive damages claim); *Guernsey v. County Living Personal Care Home, Inc.*, 2006 U.S. Dist. LEXIS 31450, 2006 WL 1412765 (M.D. Pa. 2006) (punitive damages recoverable from nursing home officials who allowed resident to have access to room of 86-year old Alzheimer’s patient where he repeatedly raped her, since nursing home was aware of resident’s prior criminal convictions for sex registration as a sexual offender under Megan’s Law, and his prior instances of grabbing and kissing staff); *Lawrence v. Kunkle*, 75 D. & C. 4th 370 (Pa. Com. Pl. 2005) (patient could maintain punitive damages claim against physician who refused to perform emergency surgery because patient did not have medical insurance

even though physician knew that patient would likely suffer permanent neurologic and functional deficits if surgery was delayed).

59. All of the cases in the paragraph above set forth examples of egregious conduct, completely inapposite to the facts of the instant case.

60. The facts underlying Plaintiffs' bare assertions of oppressive, reckless, malicious and fraudulent conduct do not even remotely meet the requisite standard under Pennsylvania law that would permit an award of punitive damages. Without any factual support, the conclusory allegation that Moving Defendants was reckless is insufficiently pled and must be stricken with prejudice as to Moving Defendants, along with all allegations of reckless and similar conduct.

E. MOTION TO STRIKE PLAINTIFF-PARENT'S CLAIMS

61. Plaintiff-parent seeks to recover damages in her own right and as the parent and natural guardian of M.E.

62. Plaintiffs' Complaint includes allegations in each count against Moving Defendants in which it is averred that Plaintiff-parent "suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries." See Exhibit "A," at ¶¶ 115, 123, 132, 142 and 152.

63. However, no specific cause of action is asserted as to any damages sought on behalf of Plaintiff-parent, who is not alleged in the Complaint to have suffered any physical injuries as a result of the alleged conduct of Moving Defendants. For this reason, Plaintiff-parent's claim should be dismissed.

64. Further, even if Plaintiff-parent had properly articulated a cause of action in the Complaint to allow her to recover damages in her own right, the Second

Amended Complaint should be stricken pursuant to Pa.R.C.P. 1020(b), which provides as follows:

If persons join as plaintiffs under Rules 2228, 2229(a) or (e), the complaint shall state the cause of action, any special damage, and the demand for relief of each plaintiff in a separate count, preceded by a heading naming the parties to the causes of action therein set forth.

65. Accordingly, it is improper for Plaintiffs to plead in a single count their claims on behalf of both the Plaintiff-minor and the Plaintiff-parent, as was done in the instant Complaint. Claims on behalf of each of the Plaintiffs must be set forth in separate counts of the Complaint, specifically identifying the cause of action asserted and relief sought in each count.

66. Additionally, although the statute of limitations for claims asserted on behalf of minors are tolled until the age of majority, Plaintiff-parent's claims were not similarly tolled and were required to have been brought within two years of the alleged injury. See *Fanscali ex rel. Fanscali v. Univ. Health Center of Pittsburgh*, 563 Pa. 439 (2000); *Hathi v. Krewstown Park Apts*, 561 A.2d 1261 (Pa. Super. 1989); 42 Pa.C.S. § 5524.

67. Plaintiffs allege that M.E. was born on September 28, 2007, was fed Similac and/or Enfamil cow's milk-based products shortly after his birth at Pennsylvania Hospital, and developed NEC shortly thereafter. See Exhibit "A" at ¶¶ 11-20.

68. Thus, because Plaintiffs filed the Complaint at issue on March 24, 2022, Plaintiff-parent's claims herein are clearly time-barred based on the applicable statute of limitations and must be dismissed.

F. MOTION TO STRIKE PLAINTIFFS' COMPLAINT FOR FAILURE TO COMPLY WITH Pa.R.C.P. 1024

69. Pennsylvania Rule of Civil Procedure 1024(a) requires verification of every pleading containing a factual averment based upon the signer's personal knowledge or information and belief.

70. Rule 1024(c) requires that the verification be made by one or more of the parties filing the pleading.

71. In this case, Plaintiffs' counsel signed the verification for the Complaint, in violation of Rule 1024. See Exhibit "A."

72. Accordingly, the Complaint should be stricken for lack of an appropriate verification.

WHEREFORE, Defendants Mead Johnson & Company, LLC and Mead Johnson Nutrition Company respectfully request that this Honorable Court sustain the instant Preliminary Objections and enter the attached proposed Order.

Respectfully submitted,

TUCKER LAW GROUP, LLC

Dated: August 7, 2024

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**ALICE STILLS, on her own behalf and
as Parent and Natural Guardian of
M.E., a Minor**

**Plaintiff,
v.**

**MEAD JOHNSON & COMPANY, LLC,
et al.,**

Defendants.

**PHILADELPHIA COUNTY COURT OF
COMMON PLEAS**

**MARCH TERM, 2022
No. 02617**

**MEMORANDUM OF LAW IN SUPPORT OF PRELIMINARY OBJECTIONS OF
DEFENDANTS MEAD JOHNSON & COMPANY, LLC AND MEAD JOHNSON
NUTRITION COMPANY TO PLAINTIFFS' SECOND AMENDED COMPLAINT**

I. MATTER BEFORE THE COURT

Preliminary Objections of Defendants Mead Johnson & Company, LLC and Mead Johnson Nutrition Company (collectively, "Mead Johnson" or "Moving Defendants") to Plaintiffs' Second Amended Complaint.

This case against Mead Johnson involves speculative and unsupported allegations by Plaintiffs that the minor Plaintiff, M.E., developed a condition known as necrotizing enterocolitis (“NEC”) following his alleged ingestion of “Similac and/or Enfamil” cow’s milk-based infant human milk fortifier manufactured and sold by Mead Johnson and/or defendant Abbott Laboratories (“Abbott”). Plaintiffs have had more than two years to correct fatal pleading deficiencies. See 7/25/2023 Order Setting Amended Complaint Deadlines and 5/20/2024 Order Setting Amended Complaint Deadlines. Despite these two years, and two rounds of preliminary objections from Defendants detailing the fatal pleading deficiencies, Plaintiffs still have not identified any Mead Johnson product that M.E. purportedly ingested. Further, *the entirety* of Plaintiffs’ claims rest on their unsubstantiated conclusion that the formula consumed by M.E. is an unreasonably dangerous product.

Plaintiffs acknowledge that premature infants such as M.E. have an inherently high risk of developing NEC. See Second Amended Complaint, attached as Exhibit A, at ¶ 22 (“Preterm and low-birth-weight infants are especially susceptible to NEC because of their underdeveloped digestive systems.”). Not only is the Second Amended Complaint entirely devoid of any claims regarding specific Mead Johnson products fed to M.E., the Complaint also lacks factual support for Plaintiffs’ claim that any Mead Johnson’s product caused M.E. to develop NEC. Plaintiffs allege only that M.E. was born on a certain date; *may* have been provided one of Defendants’ infant formula products; and, at some point, developed NEC. Plaintiffs nowhere allege how cow’s milk purportedly *causes* NEC, or how the facts of M.E.’s case relate to the scientific evidence Plaintiffs cite. Pennsylvania’s procedural rules do not allow for such gaps in logic and omissions of material facts in a

complaint. *Northern Forests II, Inc. v. Keta Realty Co.*, 130 A.3d 19, 35 (Pa. Super. 2015) (requiring plaintiffs to aver sufficient facts, together with the documents and exhibits attached thereto, to make out a prima facie case as to all elements of the cause of action, in order to survive preliminary objections). Accordingly, Plaintiffs' Second Amended Complaint should be dismissed.

II. STATEMENT OF QUESTIONS PRESENTED

1. Whether this Honorable Court should dismiss Count I of Plaintiffs' Second Amended Complaint "Strict Liability for Design Defect" cause of action with prejudice because Plaintiffs' Complaint does not support the claim that cow's milk-based products are unreasonably dangerous, and Moving Defendants cannot be held liable for a defective design?

Suggested Answer in the affirmative.

2. Whether this Honorable Court should dismiss Count II of Plaintiffs' Second Amended Complaint "Strict Liability for Failure to Warn" cause of action with prejudice because Plaintiffs' Complaint does not support the claim that cow's milk-based products are unreasonable dangerous, and Moving Defendants cannot be held liable for failure-to-warn?

Suggested Answer in the affirmative.

3. Whether this Honorable Court should dismiss Count III of Plaintiffs' Second Amended Complaint "Negligence" cause of action with prejudice on the basis of absence of proof of an unreasonably dangerous product?

Suggested Answer in the affirmative.

4. Whether this Honorable Court should dismiss Count IV of Plaintiffs' Second Amended Complaint "Intentional Misrepresentation" cause of action with prejudice on the basis of absence of proof of an unreasonably dangerous product, and failure to plead any specific representation allegedly relied upon by Plaintiffs?

Suggested Answer in the affirmative.

5. Whether this Honorable Court should dismiss Count V of Plaintiffs' Second Amended Complaint "Negligent Misrepresentation" cause of action with prejudice on the basis of absence of proof of an unreasonably dangerous product, and failure to plead any specific representation allegedly relied upon by Plaintiffs?

Suggested Answer in the affirmative.

6. Whether this Honorable Court should strike Plaintiffs' Second Amended Complaint in its entirety for insufficient specificity of the facts and alleged injuries?

Suggested Answer in the affirmative.

7. Whether this Honorable Court should strike Plaintiffs' claims for punitive damages as to Moving Defendants because the Second Amended Complaint fails to plead facts providing a basis for an award of punitive damages?

Suggested Answer in the affirmative.

8. Whether this Honorable Court should strike Plaintiffs' Second Amended Complaint for failure to provide a client verification as required by Pa.R.C.P. 1024?

Suggested Answer in the affirmative.

III. INTRODUCTION AND FACTUAL BACKGROUND

Plaintiffs have filed nearly 30 essentially identical lawsuits against Mead Johnson and Abbott in Philadelphia based on claims relating to alleged ingestion of cow's milk-based products by premature infants in the hospital following their birth.¹

Plaintiffs allege that "upon information and belief" the Plaintiff-minors, including M.E., developed NEC, a gastrointestinal disorder that occurs in premature infants. See Ex. "A," at ¶ 16. Plaintiffs allege that premature infants fed with their mother's breast milk or donor breast milk are at decreased risk of developing NEC as compared with infants given cow's milk-based infant formula. See *id.* at ¶ 22.

In addition to asserting product liability claims against Moving Defendants and Co-Defendant, Abbott, Plaintiffs have alleged that the Pennsylvania Hospital of the University of Pennsylvania and the Trustees of the University of Pennsylvania ("HUP") are liable based on claims of failure to warn and corporate liability. See Plaintiffs' Complaint at Counts VI and VII. As is discussed in detail below, Plaintiffs' claims against Moving Defendants are legally and factually deficient.

In support of their theories and claims, Plaintiffs allege that studies have "confirmed that cow's milk-based feeding products cause NEC," but do not cite to or attach any studies. See Exhibit "A," at ¶ 22. Publicly available studies merely confirm what neonatologists and physicians already know: that premature infants are at high risk of NEC, and that feeding such infants with breast milk may be better at reducing the risk of NEC than cow's milk-based alternatives. See *id.* at ¶ 22.

¹ Lawsuits involving identical claims have been filed against Pennsylvania Hospital, Temple University Hospital, Albert Einstein Medical Center and Thomas Jefferson University Hospital.

In support of their theories and claims, Plaintiffs offer only vague references to unidentified “[e]xtensive scientific research, including numerous randomized controlled trials” that purportedly prove Moving Defendants’ cow’s milk-based products cause NEC in preterm and low-birth-weight infants. See *id.* Plaintiffs neither cite specifically to any randomized trial or consensus statement, nor do they explain the purported method of action by which cow’s milk-based formula products allegedly cause NEC.

In their original complaint, Plaintiffs did specifically cite five studies comparing cow’s milk-based products to breast milk, Compl. at ¶¶ 17, 18, 19, 22, and 23, a Surgeon General report on the subject, *id.* at ¶ 20, and a statement by the American Academy of Pediatrics. *Id.* at ¶ 21. Those studies, the report, and the statement purportedly reference higher rates of NEC in preterm and low birth weight infants fed cow’s milk-based diets than those fed breast milk. They do not establish or prove causation. At best, they provide support for what neonatologists around the country already know: “Using human breast milk to feed preterm infants may reduce the risk of NEC, but it does not eliminate this risk.” News Release, Am. Academy of Pediatrics, *AAP Statement In Response to NEC Lawsuits*.²

² On July 27, 2024, the American Academy of Pediatrics issued a news release that further explained:

“Part of what is so challenging about NEC is that the causes are multifaceted and not completely understood. Our science does not tell us exactly how to prevent it. . . . Special formulas designed for preterm infants provide an essential source of nutrition. Using human breast milk to feed preterm infants may reduce the risk of NEC, but it does not eliminate this risk. Donated human milk is also used when the mother’s own milk is not available in sufficient quantities, but there is not enough donated human milk to be used as the only source of nutrition for these infants. Providing special formula is a routine and necessary part of care of these preterm infants.”

Given that Plaintiffs have offered nothing but the bald assertion that there is “extensive scientific research” that Moving Defendants’ products cause NEC, Plaintiffs have failed to adequately allege that the products are unreasonably dangerous. Accordingly, they have failed to state claims for defective design and failure-to-warn. Counts I through V should be stricken.

Plaintiffs’ Complaint provides scant information regarding M.E.’s own circumstances. Plaintiffs allege that “Upon information and belief, M.E. was fed Similac and/or Enfamil cow’s milk-based products”. *Id.* at ¶ 13. Plaintiffs further allege that “upon information and belief,” M.E. developed NEC shortly after first ingesting the Moving Defendants and Co-Defendant Abbott’s products. *Id.* at ¶ 16.³

Further, the Complaint does not provide any details whatsoever regarding communications between Plaintiff-parent and medical providers at Pennsylvania Hospital of the University of Pennsylvania regarding the allegations that M.E. may have been fed with Mead Johnson and/or Abbott cow’s milk-based products in the hospital. Plaintiffs conceded in the Complaint that mothers are encouraged by their healthcare professionals to breastfeed. *Id.* at ¶ 68. However, Plaintiffs do not provide any information regarding discussions between Plaintiff-parent and any health care providers at Pennsylvania Hospital of the University of Pennsylvania related to breastfeeding and/or using cow’s

News Release, Am. Acad. of Pediatrics, AAP Statement in Response to NEC Lawsuit Verdicts (July 27, 2024), https://www.aap.org/en/news-room/news-releases/aap/2024/aap-statement-in-response-to-nec-lawsuit-verdicts/?_ga=2.95418713.417221795.1722442775-1510920779.1722442775.

³ Plaintiffs aver that Abbott sells at least seven types of products directed to preterm and/or low birth weight infants, six of which use the name Similac, and that Mead Johnson sells eight types of infant formulas using the Enfamil brand name. *Id.*, ¶¶ 62-63.

milk-based products in this case. As noted, Plaintiffs plead that Plaintiff-minor ingested formula “on information and belief” only, and similarly plead “on information and belief” that Plaintiff-minor developed NEC as a result.

Plaintiffs also do not explain how cow’s milk could be an unreasonably unsafe product. The US FDA regulates both cow’s milk and infant formula, and places no restriction on the use of cow’s milk-based products for premature infants. FDA’s statutory mandate is to prevent the sale of adulterated foods, which are defined as those that may be injurious to human health. 21 U.S.C. §342(a). Far from deeming milk injurious, but in order to “promote honesty and fair dealing in the interest of consumers” (21 U.S.C. §341), FDA has created a standard of identity for cow’s milk. See 21 C.F.R. 131.110 (standard of identity for milk.) It has elsewhere said: “First, of all foods, none surpasses milk as a single source of those dietary elements needed for the maintenance of proper health, especially in children and older citizens. For this reason, the USPHS has for many years promoted increased milk consumption. . . .” U.S. Dep’t. of Health and Human Serv. Public Health Serv. FDA, *Grade “A” Pasteurized Milk Ordinance (Grade “A” PMO)*, (2019 Revision), available at <https://www.fda.gov/media/140394/download>.

As for formula, the federal Infant Formula Act of 1980 (“IFA”) was enacted to “assure the safety and nutrition of infant formulas.” Pub. L. No. 96-359, 94 Stat. 1190. The IFA and its implementing regulations outline the requirements that infant formula must meet, including how infant formula is made, its contents and ingredients, and the labels used on its packages, 21 U.S.C. § 350a; 21 C.F.R. §§ 106-07. The IFA provides that infant formulas may only contain “substances that are safe and suitable for use in infant formula.” 21 C.F.R. § 106.40(a). Neither the IFA nor the regulations exclude cow milk as

an ingredient, and many infant formulas for sale include cow milk. (Ex. “A,” at ¶¶ 62-63); 21 C.F.R. § 106.3 (“infant formula” is a “food for infants by reason of its *simulation* of human milk”) (emphasis added). 21 U.S.C. § 350a; 21 C.F.R. §§ 107.50. Before selling any “new infant formula,” a manufacturer must (1) register with the FDA; and (2) submit a notice to the FDA at least 90 days before marketing such formula. The notice must also state that the formula contains the required vitamins and nutrients, as demonstrated by testing. 21 U.S.C. § 350a(b). These same FDA review procedures apply when a manufacturer makes a “major change” to an existing formula. 21 U.S.C. § 350a(c)(2)(B); 21 C.F.R. § 106.3.

Further, the FDA recognizes that certain infant formulas are intended for low birth weight babies (such as infants born prematurely) or infants with unusual medical or dietary problems. Indeed, such formulas have special review requirements. 21 U.S.C. § 350a(h); 21 C.F.R. § 107.50(b)(3). As with other formulas, the regulations do not exclude cow milk as an ingredient for instant formulas intended for use by an infant with a low birth weight.

In short, since (1) the scientific authorities cited by Plaintiffs do not say that cow’s milk formula *causes* NEC, (2) the Plaintiffs’ claims rest entirely on the unsupported conclusion that the product or products the hospital decided to feed M.E. allegedly cause NEC, (3) FDA recognizes cow’s milk and infant formulas as safe, and (4) since Plaintiffs have not even alleged a probability that M.E. received a Mead Johnson product, there is no basis for any claim that the product is unreasonably dangerous and/or should not be given under any circumstances to premature or low birth weight infants.

IV. ARGUMENT

A. DEMURRER FOR FAILURE TO STATE A CLAIM AS TO COUNTS I, II, III, IV & V

Pursuant to Pa.R.C.P. 1028(a)(4), a party may file preliminary objections to a complaint, in the nature of a demurrer, for legal insufficiency in a pleading. A court should grant a demurrer where, accepting as true all well pled facts, a legal cause of action cannot be maintained upon those facts. Pa.R.C.P. 1028(a)(4); See *also, Willet v. Pennsylvania Med. Catastrophe Loss Funds*, 702 A.2d 850, 853 (Pa. 1997). In this case, Counts I, II, III, IV, and V of Plaintiffs' Complaint should be stricken pursuant to this Rule, as Plaintiffs have failed to plead certain core facts with sufficient detail to survive the pleading stage. For the reasons set forth, *supra*, where Plaintiffs' fail to demonstrate Moving Defendants' cow's milk-based product was unreasonably dangerous, Plaintiffs fail to state a cause of action upon which relief can be granted at Counts I, II, III, IV, and V.

Plaintiffs allege in Counts I and II of the Complaint that Moving Defendants, "as the manufacturers and/or sellers of the products at issue in this litigation" owed Plaintiffs and the public a duty to manufacture, sell, and distribute their products in a manner that was not unreasonably dangerous and to warn of unreasonable risk of harm posed by their products. Counts I and II are based upon Plaintiffs' theory against Moving Defendants that Moving Defendants' cow's milk-based products are unreasonably dangerous, and therefore defective, for strict liability purposes, under claims of design defect and failure-to-warn. Taking these facts as pleaded by Plaintiffs as true, Plaintiffs have failed to state a claim for defective design and failed to state a claim for failure-to-warn, due to an absence of proof of that the products are indeed unreasonably dangerous.

“The law governing strict products liability actions in Pennsylvania has been developed based upon the principles outlined in Section 402A of the Second Restatement of Torts.” *High v. Pennsy Supply, Inc.*, 154 A.3d 341 (Pa. Super. 2017).

Section 402(A) provides:

- (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
 - (a) the seller is engaged in the business of selling such a product, and
 - (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
- (2) The rule stated in Subsection (1) applies although
 - (a) the seller has exercised all possible care in the preparation and sale of his product, and
 - (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

Restatement (Second) of Torts § 402(A).

To survive preliminary objections, Plaintiffs must aver sufficient facts, together with the documents and exhibits attached thereto, to make out a *prima facie* case as to all elements of the cause of action. *Northern Forests II, Inc. v. Keta Realty Co.*, 130 A.3d 19, 35 (Pa. Super. 2015).

“The threshold inquiry in all products liability cases is whether there is a defect which rendered the product unreasonably dangerous.” *Weiner v. American Honda Motor Co., Inc.*, 718 A.2d 305, 307 (Pa. Super. 1998). “A product is defective when it is not safe

for its intended use, *i.e.*, the product left the supplier's control lacking any element necessary to make it safe for its intended use.” *Id.* at 308. Whether a product is “unreasonably dangerous” is a question of law. *Id.*

Based on the foregoing, Plaintiffs must aver sufficient facts demonstrating the Moving Defendants’ products are unreasonably dangerous for their intended use, triggering Moving Defendants’ duty to warn. The only factual reference Plaintiffs make with regard to intended use is to marketing campaigns, where Defendant Manufacturers advertised that “cow’s milk-based products are necessary for proper growth and development of preterm infants.” See Exhibit “A” at ¶ 70. They have not averred sufficient facts to demonstrate that cow’s milk-based products are unreasonably dangerous for this purpose, as the studies and reports they cite in their Complaint do not say or support – based on the very allegations in the Complaint – what Plaintiffs claim they do. These studies and reports are the sole factual support that the products in question “cause” NEC, and are the foundation for their strict products liability claims of design defect and failure-to-warn.

At the outset, Plaintiffs appropriately acknowledge that “[p]reterm and low-birth-weight infants are *especially susceptible* to NEC.” See Ex. “A,” at ¶ 22 (emphasis added). Following this, Plaintiffs make the core claim of their Complaint – that cow’s milk-based feeding products cause NEC in preterm and low birth weight infants – and that “[e]xtensive scientific research, including numerous randomized controlled trials” confirm this claim. *Id.* However, the portions of the research and trials cited by Plaintiffs in their Complaint belie their core claim.

Ultimately, Plaintiffs' claim that Moving Defendants' cow's milk-based feeding products "cause" NEC and are therefore unreasonably dangerous rests upon the notion that correlation equals causation. All that Plaintiffs' Complaint demonstrates, as pleaded under these facts, is that breast milk may be protective against the risk of NEC, not that cow's milk-based alternatives affirmatively cause NEC. This proposition does not make the Moving Defendants' cow's milk-based alternatives unreasonably dangerous within the meaning of § 402(A) of the Restatement (Second) of Torts. Thus, Plaintiffs' Complaint fails to aver sufficient facts to demonstrate that Moving Defendants' products are indeed unreasonably dangerous and maintain a cause of action sounding in strict products liability. Consequently, Plaintiffs' Complaint should be stricken at Counts I, II, III, IV, and V for failure to state a claim.

B. DEMURRER FOR FAILURE TO STATE A CLAIM AS TO COUNTS IV & V

Counts IV and V of Plaintiffs' Complaint allege intentional and negligent misrepresentation, respectively, against Moving Defendants. Plaintiffs cannot maintain misrepresentation claims because they fail to allege that they received any specific representation from Moving Defendants on which they relied. In fact, as they have not even alleged that M.E. received a Mead Johnson product, they cannot claim that misrepresentations by Mead Johnson caused reliance or their purported injury.

The elements of a claim for negligent misrepresentation are: "(1) a misrepresentation of a material fact; (2) made under circumstances in which the misrepresenter ought to have known its falsity; (3) with an intent to induce another to act on it; and (4) which results in injury to a party acting in justifiable reliance on the misrepresentation." *Bilt-Rite Contractors v. Architectural Studio*, 866 A.2d 270, 277 (Pa.

2005) (quoting *Bortz v. Noon*, 556 Pa. 489, 729 A.2d 555, 561 (Pa. 1999)). Negligent misrepresentation differs from intentional misrepresentation “in that the misrepresentation must concern a material fact and the speaker need not know his or her words are untrue, but must have failed to make a reasonable investigation of the truth of these words.” *Bortz*, 729 A.2d at 561.

The elements of an intentional misrepresentation claim require: “(1) A representation; (2) which is material to the transaction at hand; (3) made falsely, with knowledge of its falsity or recklessness as to whether it is true or false; (4) with the intent of misleading another into relying on it; (5) justifiable reliance on the misrepresentation; and (6) the resulting injury was proximately caused by the reliance.” *Bortz*, 729 A.2d at 499 (citing *Gibbs v. Ernst*, 647 A.2d 882, 889 (1994), citing, Restatement (Second) of Torts § 525 (1977)).

Here, Plaintiffs’ claims fail to allege that they received any specific representation from Moving Defendants, intentional or otherwise. Plaintiffs further fail to allege that they relied on a specific representation of the Moving Defendants. Because of these omissions from Plaintiffs’ Complaint, Plaintiffs have failed to articulate a viable claim for intentional and negligent misrepresentation. *See, e.g., Cruz v. Roberts*, No. CI-04-01947, 2005 Pa. Dist. & Cnty. Dec. LEXIS 186, 70 Pa. D. & C.4th 225 (Pa. CCP Jan. 26, 2005) (dismissing negligent and intentional misrepresentation claims for insufficient pleading); *see also Kepner v. Tine*, No. 835 EDA 2015, 2015 Pa. Super. Unpub. LEXIS 4257 (Pa. Super. Nov. 25, 2015) (dismissing fraudulent misrepresentation claim for failure to plead a particular misrepresentation).

Thus, Plaintiffs' intentional and negligent misrepresentation claims against Moving Defendants must be dismissed.

C. MOTION TO STRIKE PLAINTIFFS' COMPLAINT FOR INSUFFICIENT SPECIFICITY AS TO THE FACTS AND ALLEGED INJURIES

Pursuant to Pa.R.C.P. 1028(a)(3), a party may file preliminary objections in the nature of a motion to strike for insufficient specificity in a pleading. A plaintiff's Complaint is required to provide a defendant with notice of what the plaintiff's claims are and the grounds upon which they rest, and the Complaint must also formulate the issues by summarizing the facts essential to support the claims. *Alpha Tau Omega Fraternity v. The University of Pennsylvania*, 464 A.2d 1349, 1352 (Pa. Super. 1983) (citations omitted). Pennsylvania Rule of Civil Procedure 1019(a) provides that "the material facts on which a cause of action or defense is based shall be stated in a concise and summary form." Pa.R.C.P. 1019(a). As the Superior Court has noted,

Rule 1019(a) requires fact pleading. The purpose of 1019(a) is to require the pleader to disclose the material facts sufficient to enable the adverse party to prepare his case. **A complaint therefore must do more than give the defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests. It should formulate the issues by fully summarizing the material facts. Material facts are ultimate facts, i.e., those facts essential to support the claim. Evidence from which such facts may be inferred not only need not but should not be alleged. Allegations will withstand challenge under 1019(a) if (1) they contain averments of all of the facts a plaintiff will eventually have to prove in order to recover, and (2) they are sufficiently specific so as to enable defendant to prepare his defense.**

Baker v. Rangos, 324 A.2d 498, 505-506 (Pa. Super. 1974) (citations and internal quotations omitted) (emphasis added).

Further, it is well established that, with regard to the description of injuries sustained by a plaintiff, the Complaint must be stated with sufficient particularity to put the defendant on notice of evidence that may be produced at trial. *Kelly v. Martino*, 99 A.2d 901 (Pa. 1953). **A plaintiff's Complaint must set forth the extent, nature, location and duration of the injuries suffered, and injuries that are permanent should be stated specifically.** *Miller v. Perrige*, 71 Pa. D. & C.2d 476, 479–80 (Pa. Com. Pl. 1975). See, also, *Kopan v. Hawk*, 14 Pa. D. & C.2d 713, 714 (Pa. Com. Pl. 1958) (“A catchall averment of “other injuries” is nothing more than a generalized averment under which any injuries whatever could be proved at the trial. Defendant would have no knowledge in advance of the trial of what they are.”)

Plaintiffs' Complaint is facially deficient with regard to the specificity of the allegations of the relevant facts and injuries at issue in this case.⁴ Plaintiffs' description of the material facts relating to the minor's care and treatment, diagnosis and injuries is limited to four paragraphs, which are utterly insufficient to enable defendants to prepare their defenses. See Ex. “A,” at ¶¶ 11-20. Plaintiffs' allegation that “upon information and belief,” the minor was fed Similac and/or Enfamil shortly after his birth (*Id.* at ¶ 13) does not comply with the fact-pleading requirements of Rule 1019(a), since such allegations do not provide Moving Defendants with appropriate notice of the facts as to whether the minor actually ingested cow's milk-based products. Further, Plaintiffs have failed to

⁴ Plaintiffs' complaint violates the most basic pleading rules. It is procedurally deficient and bereft of relevant substantive support. Relying upon vague place-holder pleading conventions (e.g., “upon information and belief,” “and/or”) and citation to inapposite scientific studies, Plaintiffs' complaint is replete with supposition, leaps in logic and unsubstantiated innuendo. The Court should not countenance such flouting of the rules.

identify which of the numerous products sold by Abbott and Mead Johnson under the Similac and Enfamil brand names were ingested by the minor. *Id.* at ¶¶ 62-63. Plaintiffs' Complaint further fails to provide a description of the material facts as to the period of time in which such products were ingested, when the minor was allegedly diagnosed with NEC and what treatment was provided for that condition.

In short, Plaintiffs' Complaint is inconsistent with the requirements of the Pennsylvania Rules of Civil Procedure as to the necessary specificity for the description of the facts and alleged injuries sustained. The facts in the Complaint are pleaded almost entirely "on information and belief." These omissions are fatal defects in Plaintiff's Complaint. Therefore, Plaintiffs' Complaint should be stricken in its entirety.

D. MOTION TO STRIKE PLAINTIFFS' CLAIMS FOR PUNITIVE DAMAGES

As in the other infant formula cases, In the *Ad Damnum* clauses of Counts I, II, III, IV, and V of the Complaint, Plaintiffs make baseless accusations that Moving Defendants engaged in oppressive, reckless, malicious and/or fraudulent conduct that allegedly justify an award of punitive damages. See Ex. "A," at ¶¶ 115, 123, 132, 142 and 152. However, the Complaint contains no specific allegations of conduct that would permit recovery of punitive damages as to Moving Defendants. Rather, Plaintiffs merely allege that "upon information and belief" M.E. may have been given a cow's milk-based infant fortifier following birth, absent any context to indicate that such an action was inappropriate based on the specific issues involved in M.E.'s medical care and condition following birth. For example, the Complaint gives no indication of whether Plaintiff-parent refused or was unable to provide breast milk and provides no information as to discussions between her and any health care providers regarding the purported use of cow's milk-based products.

Plaintiffs' allegations of oppressive, malicious and similar conduct must be rejected as mere boilerplate. As discussed above, the FDA specifically approves the use of infant formula in care of low birth weight infants, with no restriction as to the use of cow's milk-based products for such infants. Indeed, the fact that Plaintiffs have filed numerous lawsuits against at least four other hospitals in Philadelphia based on identical claims belies the contention that Moving Defendants engaged in outrageous or malicious conduct in allegedly feeding the Plaintiff-minor with cow's milk-based infant formula. Absent specific factual allegations to justify the claim that the use of infant formula in M.E.'s case was extreme and outrageous, there is no basis for an award of punitive damages in this case. Merely contending that punitive damages should be awarded with no supporting factual justification requires dismissal of this claim.

Since the purpose of punitive damages is not compensation of a plaintiff but punishment of the defendant and deterrence, punitive damages can be awarded only for conduct involving some element of outrage. *Hutchinson v. Luddy*, 582 Pa. 114, 870 A.2d 766 (2005). For that reason, Pennsylvania Supreme Court decisions establish that "punitive damages are an 'extreme remedy' available in only the most exceptional matters." *Wagner v. Onofrey*, 2006 Pa. Dist. & Cnty. Dec. LEXIS 333, *11 (Pa. Com. Pl. 2006) (citing *Phillips v. Cricket Lighters*, 584 Pa. 179, 188, 883 A.2d 439, 445 (2005)). "In fact, punitive damages are specifically designed to heap an additional punishment on a defendant who is found to have acted in a fashion which is particularly egregious." *Wagner* at *12.

Punitive damages may not be awarded for misconduct that constitutes ordinary negligence such as inadvertence, mistake and errors of judgment. *Martin v. Johns-*

Manville Corp., 494 A.2d 1088, 1097 (Pa. 1985); *McDaniel v. Merck, Sharp & Dohme*, 533 A.2d 436, 437 (Pa. Super. 1987). An award of punitive damages must be supported by evidence of conduct more serious than the mere commission of the underlying tort. *Allstate Ins. Co. v. A.M. Pugh Assoc., Inc.*, 604 F. Supp. 85, 99 (M.D. Pa. 1984).

The Supreme Court has made clear that when assessing the propriety of the imposition of punitive damages, “the state of mind of the actor is vital. The act or failure to act, must be intentional, reckless or malicious.” *Hutchinson, supra* at 770. An appreciation of the risk is a necessary element of the mental state required for the imposition of punitive damages. *Id.* at 772. Thus, “a punitive damages claim must be supported by evidence sufficient to establish that (1) a defendant had a subjective appreciation of the risk of harm to which the plaintiff was exposed and that (2) he acted, or failed to act, as the case may be, in conscious disregard of that risk.” *Id.*

Where the facts as averred show nothing more than negligence, a lapse in judgment, or mere inadvertence, courts in Pennsylvania have dismissed pleas and claims for punitive damages, often at the pleadings stage of litigation and even if the complaint alleged severe injuries or death. *See, e.g., Brownawell v. Bryan*, 40 Pa. D. & C.3d 604, 606 (Pa. Com. Pl. 1985) (dismissing punitive damages claim where a plaintiff alleged that a physician negligently performed a spinal fusion surgery that left the plaintiff with severe neurological defects, and noting that “**the mere pleading of outrageous conduct** does not, of course, satisfy the requirement stating facts which, if proven, would form a basis for a jury concluding that the conduct was such that an award of punitive damages was warranted.”) (emphasis added); *Wagner, supra* at *11 (contentions that physician failed to prescribe antibiotics, order certain tests or request an infectious disease consult

constituted “nothing more than ordinary negligence and are insufficient to support an award of punitive damages.”); *McCardle v. Aldinger*, 5 Pa. D. & C.4th 421, 428 (Pa. Com. Pl. 1996) (sustaining preliminary objections and dismissing claim for punitive damages where the plaintiff alleged negligence in the prenatal care of her child that led to the child was stillborn and holding that “[i]t is not the outcome of the alleged negligence that is of consideration, but rather the alleged conduct of defendants that is at issue.”); *Flurer v. Pocono Medical Ctr.*, 15 Pa. D. & C.4th 645, 670 (Pa. Com. Pl. 1992) (sustaining preliminary objections and finding that plaintiffs were not “capable of pleading the requisite behavior” for an award of punitive damages where a hospital allegedly failed to properly utilize a fetal monitor on a pregnant woman who was involved in a serious car accident and thereafter delivered a stillborn child).

Conversely, punitive damages have been reserved for those situations that are truly egregious and utterly outrageous, and typically involve aggravating or other factors that evince a particularly reckless mind or evil motive. *See, e.g., Medvecz v. Choi*, 569 F.2d 1221, 1227-30 (3rd Cir. 1987) (anesthesiologist who abandoned patient on operating room table and left room for a lunch break without securing a suitable replacement could be liable for punitive damages to patient who suffered irreversible paralysis from anesthesia complication that developed during his absence); *Hoffman v. Memorial Osteopathic Hospital*, 492 A.2d 1382, 386-87 (Pa. Super. 1985) (evidence that emergency room physician allowed Guillain-Barre Syndrome patient suffering from neurological paralysis to remain crying and immobile on floor for two hours as physician repeatedly stepped over patient was sufficient to support punitive damages claim); *Guernsey v. County Living Personal Care Home, Inc.*, 2006 U.S. Dist. LEXIS 31450, 2006

WL 1412765 (M.D. Pa. 2006) (punitive damages recoverable from nursing home officials who allowed resident to have access to room of 86-year old Alzheimer's patient where he repeatedly raped her, since nursing home was aware of resident's prior criminal convictions for sex registration as a sexual offender under Megan's Law, and his prior instances of grabbing and kissing staff); *Lawrence v. Kunkle*, 75 D. & C. 4th 370 (Pa. Com. Pl. 2005) (patient could maintain punitive damages claim against physician who refused to perform emergency surgery because patient did not have medical insurance even though physician knew that patient would likely suffer permanent neurologic and functional deficits if surgery was delayed).

All of the cases in the paragraph above set forth examples of egregious conduct, completely inapposite to the facts of the instant case. The facts underlying Plaintiffs' bare assertions of reckless, outrageous or similar behavior do not even remotely meet the requisite standard under Pennsylvania law that would permit an award of punitive damages. Without any factual support, the conclusory allegation that Moving Defendants were reckless is insufficiently pled and must be stricken from the Complaint pursuant to Rule 1028(a)(3).

E. MOTION TO STRIKE PLAINTIFF-PARENT'S CLAIMS

Plaintiff-parent seeks to recover damages in her own right and as the parent and natural guardian of M.E. Her claims should be dismissed for the reasons set forth below.

Plaintiffs' Complaint includes allegations in each count against Moving Defendants in which it is averred that Plaintiff-parent "suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries." See Exhibit "A," ¶¶ 115, 123, 132, 142 and 152. However, no specific cause of

action is asserted as to any damages sought on behalf of Plaintiff-parent, who is not alleged in the Complaint to have suffered any physical injuries as a result of the alleged conduct of Moving Defendants.

Further, even if Plaintiff-parent had properly articulated a cause of action in the Complaint to allow her to recover damages in her own right, the Complaint should be stricken pursuant to Pa.R.C.P. 1020(b), which provides as follows:

If persons join as plaintiffs under Rules 2228, 2229(a) or (e), the complaint shall state the cause of action, any special damage, and the demand for relief of each plaintiff in a separate count, preceded by a heading naming the parties to the causes of action therein set forth.

Accordingly, it is improper for Plaintiffs to plead in a single count their claims on behalf of both the Plaintiff-minor and the Plaintiff-parent, as was done in the instant Complaint. Claims on behalf of each of the Plaintiffs must be set forth in separate counts of the Complaint, specifically identifying the cause of action asserted and relief sought in each count.

Additionally, although the statute of limitations for claims asserted on behalf of minors are tolled until the age of majority, Plaintiff-parent's claims were not similarly tolled and were required to have been brought within two years of the alleged injury. See *Fanscali ex rel. Fanscali v. Univ. Health Center of Pittsburgh*, 563 Pa. 439 (2000); *Hathi v. Krewstown Park Apts*, 561 A.2d 1261 (Pa. Super. 1989); 42 Pa.C.S. § 5524. Plaintiffs allege that M.E. was born on January 18, 2007, was fed Similac and/or Enfamil cow's milk-based products shortly after his birth at Pennsylvania Hospital, and developed NEC shortly thereafter. See Exhibit "A," ¶¶ 11-20. Thus, because Plaintiffs filed their original Complaint on March 24, 2022, Plaintiff-parent's claims herein are clearly time-barred based on the applicable statute of limitations and must be dismissed.

F. MOTION TO STRIKE PLAINTIFFS' COMPLAINT FOR FAILURE TO COMPLY WITH Pa.R.C.P. 1024

Pennsylvania Rule of Civil Procedure 1024(a) requires verification of every pleading containing a factual averment based upon the signer's personal knowledge or information and belief. Rule 1024(c) requires that the verification be made by one or more of the parties filing the pleading. In this case, Plaintiffs' counsel signed the verification for the Complaint, in violation of Rule 1024. See Exhibit "A." Accordingly, the Complaint should be stricken for lack of an appropriate verification.

V. REQUESTED RELIEF

For the foregoing reasons, Defendants Mead Johnson & Company, LLC and Mead Johnson Nutrition Company respectfully request that this Honorable Court sustain their Preliminary Objections and enter the attached Order.

Respectfully submitted,

TUCKER LAW GROUP, LLC

Dated: August 7, 2024

/s/ Kenneth A. Murphy
Kenneth A. Murphy, Esquire

WELSH & RECKER, P.C.

/s/ Catherine M. Recker
Catherine M. Recker, Esquire
Amy B. Carver, Esquire
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**Attorneys for Defendants,
Mead Johnson & Company, LLC and
Mead Johnson Nutrition Company**

CERTIFICATE OF SERVICE

I, Kenneth A. Murphy, Esquire, do hereby certify that on this day I caused a true and correct copy of the foregoing Preliminary Objections of Defendants Mead Johnson & Company and Mead Johnson Nutrition Company to Plaintiffs' Complaint, and accompanying Memorandum of Law, to be served via electronic filing, on the following counsel of record, addressed as follows:

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By: /s/ Kenneth A. Murphy
Kenneth A. Murphy, Esquire

Dated: August 7, 2024

Exhibit A

<p>NOTICE</p> <p>You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so the case may proceed without you and a judgment may be entered against you by the court without further notice for any money claimed in the complaint or for any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.</p> <p>YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW. THIS OFFICE CAN PROVIDE YOU WITH INFORMATION ABOUT HIRING A LAWYER.</p> <p>IF YOU CANNOT AFFORD TO HIRE A LAWYER, THIS OFFICE MAY BE ABLE TO PROVIDE YOU WITH INFORMATION ABOUT AGENCIES THAT MAY OFFER LEGAL SERVICES TO ELIGIBLE PERSONS AT A REDUCED FEE OR NO FEE.</p> <p>Lackawanna Bar Association 233 Penn Avenue Scranton, PA 18503 (570) 961-2714</p>	<p>ADVISO</p> <p>Le han demandado a usted en la corte. Si usted quiere defenderse de estas demandas expuestas en las paginas siguientes, usted tiene veinte (20) días de plazo al partir de la fecha de la demanda y la notificación. Hace falta asentar una comparencia escrita o en persona o con un abogado y entregar a la corte en forma escrita sus defensas o sus objeciones a las demandas en contra de su persona. Sea avisado que si usted no se defiende, la corte tomara medidas y puede continuar la demanda en contra suya sin previo aviso o notificación. Además, la corte pueda decidir a favor del demandante y requiere que usted cumpla con todas las provisiones de esta demanda. Usted puede perder dinero o sus propiedades u otros derechos importantes para usted.</p> <p>LLEVE ESTA DEMANDA A UN ABOGADO INMEDIATAMENTE, SI NO TIENE ABOGADO O SI NO TIENE EL DINERO SUFICIENTE DE PAGAR TAL SERVICIO, VAYA EN PERSONA O LLAME POR TELEFONO A LA OFICINA CUYA DIRECCION SE ENCUENTRA ESCRITA ABAJO PARA AVERIGUAR DONDE SE PUEDE CONSEGUIR ASISTENCIA LEGAL.</p> <p>Colegio de Abogados del Lackawanna 233 Penn Avenue, Scranton, PA 18503 (570) 961-2714</p>
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KLINE & SPECTER, P.C.

By:

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<div style="border: 1px solid black; padding: 10px;"><p>ALICE STILLS, on her own behalf and as Parent and Natural Guardian of M.E., a Minor,</p><p style="text-align: center;"><i>Plaintiff,</i></p><p style="text-align: center;">v.</p><p>MEAD JOHNSON & COMPANY, LLC, MEAD JOHNSON NUTRITION COMPANY, ABBOTT LABORATORIES, THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA d/b/a PENN MEDICINE, and PENNSYLVANIA HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM d/b/a PENNSYLVANIA HOSPITAL,</p><p style="text-align: center;"><i>Defendants.</i></p></div>	<p>: IN THE COURT OF COMMON PLEAS</p> <p>: PHILADELPHIA COUNTY</p> <p>:</p> <p>: CIVIL TRIAL DIVISION</p> <p>:</p> <p>: MARCH TERM 2022</p> <p>: NO. 02617</p> <p>:</p> <p>:</p> <p>:</p> <p>:</p> <p>:</p> <p>:</p> <p>:</p> <p>:</p> <p>:</p> <p>:</p> <p>:</p> <p>:</p>
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SECOND AMENDED COMPLAINT

Plaintiff brings this Second Amended Complaint and Demand for Jury Trial (the “Second Amended Complaint”) against Mead Johnson & Company, LLC, Mead Johnson Nutrition Company, and Abbott Laboratories (collectively “the Defendant Manufacturers”), and The Trustees of the University of Pennsylvania d/b/a Penn Medicine and Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital (collectively “Penn

Medicine” or “Pennsylvania Hospital”), together “Defendants.” Plaintiff alleges the following upon personal knowledge as to Plaintiff’s own acts and experiences and upon information and belief, including investigation conducted by Plaintiff’s attorneys, as to all other matters.

I. INTRODUCTION

1. This action arises out of the injuries suffered by a premature infant (the “Injured Infant”) who was given the Defendant Manufacturers’ cow’s milk-based infant feeding products at Pennsylvania Hospital. Pennsylvania Hospital, managed by Penn Medicine, acquired and supplied the Defendant Manufacturers’ products to the Injured Infant and negligently failed to warn of their unreasonably dangerous properties in a reasonable manner. This caused the Injured Infant to develop necrotizing enterocolitis (“NEC”), a life-altering and potentially deadly disease that largely affects premature babies who are given cow’s milk-based feeding products. As a result, the Injured Infant was seriously injured, resulting in long term health effects and accompanying harm to their parent (“the Plaintiff Parent”).

2. Plaintiff brings these causes of action against Defendants to recover for injuries that are the direct and proximate result of the Injured Infant’s consumption of the Defendant Manufacturers’ unreasonably dangerous cow’s milk-based infant feeding products, which were acquired and supplied without adequate warning to the Injured Infant at Pennsylvania Hospital, owned and operated by Penn Medicine.

II. PARTIES

3. Plaintiff Alice Stills is a natural adult person and a resident of Pennsylvania. Ms. Stills is the parent and natural guardian of M.E., a minor. Ms. Stills’s address is 656 N. Conestoga Street, Philadelphia, Pennsylvania 19131.

4. Defendant Mead Johnson Nutrition Company is a corporation, incorporated under the laws

of the State of Delaware. Its principal place of business is Illinois. Defendant Mead Johnson & Company, LLC, is a limited liability company, organized under the laws of the State of Delaware. Its citizenship is that of its sole member, Mead Johnson Nutrition Company. Defendants Mead Johnson Nutrition Company and Mead Johnson & Company, LLC, (together, “Mead”) are manufacturers of cow’s milk-based infant feeding products and market many of these products under the “Enfamil” brand name.

5. Defendant Abbott Laboratories (“Abbott”) is a corporation, incorporated under the laws of the State of Illinois. Its principal place of business is in Illinois. Abbott is a manufacturer of cow’s milk-based infant feeding products and markets many of its products under the “Similac” brand name.

6. Defendant The Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital is a non-profit corporation incorporated and registered to do business under the laws of the Commonwealth of Pennsylvania. Its principal place of business is Philadelphia, Pennsylvania. Pennsylvania Hospital is a registered name of The Pennsylvania Hospital of the University of Pennsylvania Health System. The sole member of The Pennsylvania Hospital of the University of Pennsylvania Health System is The Trustees of the University of Pennsylvania.

7. Defendant The Trustees of the University of Pennsylvania d/b/a Penn Medicine is a non-profit corporation registered to do business in the Commonwealth of Pennsylvania. Its principal place of business is Philadelphia, Pennsylvania. Penn Medicine is a registered name of The Trustees of the University of Pennsylvania.

III. JURISDICTION AND VENUE

8. This Court has jurisdiction in this matter pursuant to 42 Pa. C.S.A. § 931. Defendants

conduct authorized business in the Commonwealth of Pennsylvania. They have sufficient minimum contacts with and purposefully avail themselves of the markets of this Commonwealth. This suit arises out of Defendants' forum-related activities, such that the Court of Common Pleas of Philadelphia County's exercise of jurisdiction would be consistent with traditional notions of fair play and substantial justice.

9. Venue is proper in the Court of Common Pleas of Philadelphia County pursuant to Rules 1006(b), 1006(c)(1), and 2179(a) of the Pennsylvania Rules of Civil Procedure because Defendants are corporations or similar entities that regularly conduct business in Philadelphia County, which is also the county where Plaintiff's causes of action arose, and the county where the occurrences took place out of which Plaintiff's causes of action arose.

10. This action is not subject to the Compulsory Arbitration Program of the Court of Common Pleas of Philadelphia County because the amount in controversy, excluding interest and costs, is in excess of \$50,000.

IV. FACTUAL ALLEGATIONS

M.E.'s NEC Diagnosis

11. M.E. was born premature at Pennsylvania Hospital in Philadelphia, Pennsylvania on September 28, 2007.

12. At birth, M.E.'s gestational age was approximately 28 weeks and he weighed 622 grams, making him an extremely low birth weight infant.

13. Upon information and belief M.E. was fed Similac and/or Enfamil cow's milk-based products by staff at Pennsylvania Hospital from shortly after her birth despite the fact that Pennsylvania Hospital knew or should have known that cow's milk-based products increase the risk of NEC and that human milk decreases the risk of NEC.

14. Specifically, beginning on September 29, 2007, Dr. Thomas Mollen ordered that M.E. was to be fed mother's breast milk which was then fortified with bovine-based human milk fortifier (HMF) in order to be 24 cal/oz, which based upon information and belief was manufactured by Defendant Abbott Laboratories and/or Defendant Mead Johnson.

15. Further, upon information and belief, no later than October 29, 2007, Dr. Mollen revised his nutritional orders to start feeding infant M.E. Abbot's "Special Care" bovine based formula, which M.E. was ultimately fed for a total of 31 days while under the care of Pennsylvania Hospital.

16. On November 2, 2007, M.E. was diagnosed in the Pennsylvania Hospital NIC-U with stage II-B Medical NEC, and thereafter was transferred to Children's Hospital of Philadelphia (CHOP) for management of Medical NEC. M.E. was treated for Medical NEC at CHOP between November 2 to November 8, 2007

17. November 8, 2007, when M.E. was discharged from CHOP and returned to the Pennsylvania Hospital NICU, the treating physicians at the Pennsylvania Hospital NICU revised his nutritional orders to start feeding infant M.E. Abbot's "Neosure" bovine based formula for a total of another 8 days, after which they switched back to Abbott's "Special Care".

18. These feeds all occurred despite the fact that Pennsylvania Hospital knew or should have known that cow's milk-based products, including formula and human milk fortifier, increase the risk of NEC and that human milk can decrease the risk of NEC.

19. On December 5, 2007 M.E. was discharged from the Pennsylvania Hospital NICU, and Plaintiff parent was given the recommendation to continue feeding with Neosure, as well as samples of the product.

20. As a result of the Stage II-B Medical NEC diagnosis, infant M.E. experienced permanent developmental delay, including but not limited to neurodevelopmental impairment (NDI).

Cow's Milk-Based Feeding Products Are Known to Cause NEC

21. NEC is a devastating disease that is the most frequent and lethal gastrointestinal disorder affecting preterm infants. NEC develops when harmful bacteria breach the walls of the intestine, causing portions of the intestine to become inflamed and often to die. Once NEC develops, the condition can progress rapidly from mild feeding intolerance to systemic and fatal sepsis. Up to 30 percent of NEC-diagnosed infants die from the disease.

22. Preterm and low-birth-weight infants are especially susceptible to NEC because of their underdeveloped digestive systems. Extensive scientific research, including numerous randomized controlled trials, has confirmed that cow's milk-based feeding products cause NEC in preterm and low-birth-weight infants, which in turn may lead to other medical complications, surgeries, long-term health problems, and death.

Safer, Nutritionally Superior Alternatives to Cow's Milk-Based Products Exist

23. A range of options are available that allow preterm and low-birth-weight infants to be fed exclusively human milk-based nutrition. For example, in addition to the mother's own milk, an established network delivers pasteurized donor breast milk to hospitals nationwide. Moreover, hospitals have access to shelf-stable formula and fortifiers derived from pasteurized breast milk.

24. A diet based exclusively on breast milk and breast milk fortifiers provides all the nutrition necessary to support premature and low-birth-weight infants without the elevated risk of NEC associated with cow's milk-based products.

25. The Defendant Manufacturers' products not only pose a threat to infants' health, but also displace the human milk they could otherwise receive. This displacement only increases infants' vulnerability to NEC.

26. Human milk-based nutrition nourishes infants while creating a significantly lower risk of

NEC.

27. At the time the Injured Infant was fed the Defendant Manufacturers' products, the science clearly demonstrated to Defendants that these products cause NEC and greatly increase the likelihood that a baby will develop NEC, leading to severe injury and often death.

28. Despite the scientific evidence that the Defendant Manufacturers' cow's milk-based products present a dire threat to the health and development of preterm infants, the Defendant Manufacturers have made no changes to their products or the products' packaging, guidelines, instructions, or warnings. Instead, they have continued to sell their unreasonably dangerous products. In addition, they incentivize hospitals that know the risks to use their products by providing them to the hospital for free or at a significant discount, in order that vulnerable infants and their families will become accustomed to using their products before discharge. And, in fact, the Defendant Manufacturers offer contracts to hospitals—which the hospitals accept—that actually *prevent* the health care providers from offering alternative products—even safer ones—on pain of risking the hospital's advantageous formula pricing strategy.

29. Despite the scientific evidence that the Defendant Manufacturers' cow's milk-based products present a dire threat to the health and development of preterm infants and Pennsylvania Hospital knew or should have known of that threat, staff of Pennsylvania Hospital fed Similac and/or Enfamil cow's milk-based products after her birth instead of mother's human milk and/or donor human milk.

30. Despite the scientific evidence that the Defendant Manufacturers' cow's milk-based products present a dire threat to the health and development of preterm infants and Pennsylvania Hospital knew or should have known of that threat, staff of Pennsylvania Hospital did not properly warn Ms. Wiger of those risks and alternatives to have avoided the cow's milk-based products.

Ms. Stills Discovers Her Claim

31. Because of the Defendants' concealment and misrepresentations, described more fully herein, Ms. Stills did not know, and had no reason to know or suspect, that M.E.'s NEC could have been caused by the Defendant Manufacturers' products.

***Despite Exercising Diligence, a Reasonable Investigation Did Not Reveal and
Would Not Have Revealed a Factual Basis Earlier
Because Defendants Hid the Cause of NEC from Ms. Stills***

32. Despite exercising reasonable diligence, Ms. Stills was unable to have made the discovery earlier via a reasonable investigation because the Defendants in this litigation concealed the wrongful cause of M.E.'s injuries.

33. Amidst the physical and emotional trauma of preterm childbirth, and having her child in the neonatal intensive care unit, shortly after learning of M.E.'s NEC diagnosis, Ms. Stills undertook an investigation into the cause of the NEC by asking the doctors the cause of her NEC.

34. The health care providers at Penn Medicine responded only that M.E. had gotten NEC because he was born premature. Penn Medicine's response did not indicate that her NEC was caused by the Defendant Manufacturers' products.

35. Not one person at Penn Medicine mentioned that the Defendant Manufacturers' formula products could have caused M.E.'s injuries. Penn Medicine's response at the time did not give Ms. Stills any reason to suspect any wrongdoing on the part of the Defendants.

36. Ms. Stills is a layperson with no medical background or training that would have given her any reason to doubt the response she received from her Penn Medicine health care providers at the time.

37. Given that Penn Medicine's health care providers were in charge of the care of her newborn infant, Ms. Stills had no reason to doubt their word.

38. Additionally, the risk of necrotizing enterocolitis was not disclosed on the labeling or packaging of *any* of the Defendant Manufacturers' products.

39. What is more, necrotizing enterocolitis is a disease that can occur in children who are *not* fed the Defendant Manufacturers' products, and the Defendant Manufacturers have worked to mislead parents into a false sense of security about the use of those products. Publicly disseminated materials from each Defendant Manufacturer disguise the role their products play in causing the disease—and affirmatively say, even today, that their products are safe and do not cause NEC. In fact, some publicly disseminated materials from the formula manufacturers even suggest that formula may help *reduce* the risk of this terrible and potentially fatal disease.

40. For example, Abbott's website says that "[t]he specific cause of NEC is unknown, but it's most often seen in very low birth weight premature babies," and that "about 10% of babies who are born prematurely develop NEC." The website suggests that "new preliminary studies" suggest for the first time that "NEC prevention may . . . be possible" with the use of human milk oligosaccharides to "dramatically curb intestinal inflammation" and reduce the risk of NEC. Abbott states that these human milk oligosaccharides are found in "certain Similac formulas" although they are "not currently available in Similac's premature infant formulas."¹ Likewise, the website for Mead Johnson's products states that necrotizing enterocolitis is "one of the most common and serious intestinal disease[s] among premature babies." And it deflects responsibility from Mead Johnson's products: "Necrotizing enterocolitis happens when tissue in the small or large intestine is injured or inflamed."²

¹ The Role of HMOs in Reducing NEC, <https://www.nutritionnews.abbott/pregnancy-childhood/prenatal-breastfeeding/the-promising-role-of-hmos-in-reducing-risk-of-nec/> (last visited July 28, 2023).

² Special Feeding Concerns for Preemies, <https://www.enfamil.com/articles/special-feeding-concerns-for-preemies/> (last visited July 29, 2023).

41. Because of the misleading information distributed by the Defendant Manufacturers, as further detailed *infra*, any research conducted by Ms. Stills immediately after M.E.'s diagnosis, or at any time prior to seeing an advertisement, would not have led a reasonable person to suspect that the Defendant Manufacturers' products could have caused M.E.'s injuries.

42. Ms. Stills also did not know, and had no reason to know or suspect, that Penn Medicine breached its duty of care by distributing the Defendant Manufacturers' products to her. Not only was Ms. Stills unaware that the Defendant Manufacturers' products caused M.E.'s injuries, but the Defendant Manufacturers' distribution agreements with Penn Medicine—which allowed Penn Medicine to secure sweetheart deals for otherwise expensive premature infant formula in exchange for product placement and access to the hospital staff—were also not public or knowable to Ms. Stills, nor could any reasonable investigation outside of litigation have uncovered the terms of those agreements.

Despite Exercising Reasonable Diligence, the Defendants' Fraudulently Concealed the Risks of NEC from Defendant Manufacturers' Products to Divert, Prevent, and Mislead Plaintiff Regarding the Cause of Her Child's NEC Diagnosis

43. In addition to the averments above, the Defendants have acted in concert to fraudulently convey false and misleading information concerning the risk of NEC, and potentially death, caused by Defendant Manufacturers' preterm infant formula products.

44. The Defendants' actions as set forth herein constitute knowing misrepresentation, omission, suppression, and concealment of material facts, made with the intent that Plaintiff would rely upon such concealment, suppression, or omission, in connection with the use of Defendants' preterm infant products.

45. Plaintiff did not know, and could not learn, the truth concerning the uses, risks and benefits of Defendant Manufacturers' preterm infant products due to Defendants' deliberate

misrepresentations and concealment, suppression and omission of material facts and important information regarding the risks of NEC, and potentially death, from the products.

46. Moreover, Defendant Hospital further participated in the intentional concealment—on information and belief, it allowed the Defendant Manufacturers’ sales representatives into its hospital to provide samples and free products that did not warn of their serious dangers, and to provide “education” to its NICU staff that was incomplete as to the true risks of feeding their patients the Defendant Manufacturers’ products.

47. Based upon information and belief, during the relevant time period, Pennsylvania Hospital, Penn Medicine, and the Hospital of the University of Pennsylvania stocked formula products from both Abbott and Mead.

48. Additionally, Defendant Hospital failed to inform Ms. Stills that the Defendant Manufacturers’ products caused Plaintiff’s NEC, even when she directly asked the cause. As noted above, after learning of Plaintiff’s NEC diagnosis, Ms. Stills was understandably concerned about the degrading health of her newborn infant. As any concerned parent would do, Ms. Stills asked Plaintiff’s health care providers at Defendant Hospital why a premature infant like M.E. was suddenly diagnosed with a terrible disease like necrotizing enterocolitis; that is, she asked Defendant Hospital what caused Plaintiff’s injury. But even though Defendant Hospital knew of the increased risk of NEC from formula, it did not disclose that the formula provided to M.E. could increase the risk of NEC to preterm infants, responding only that M.E. had gotten NEC solely because she was born premature. Not one person at the NICU mentioned that the Defendant Manufacturers’ formula products could have been the cause of Plaintiff’s injuries.

49. Defendant Hospital was aware that the Defendant Manufacturers’ products caused NEC in premature infants. Defendant Hospital was also aware that the Defendant Manufacturers did not

provide warnings on their products. However, Defendant Hospital did not warn Ms. Stills of the risks of the products. Instead, and notwithstanding the sweetheart deal Defendant Hospital agreed to in exchange for preterm infant formula at little to no cost, Defendant Hospital repeatedly informed Ms. Stills that it would do everything it could possibly do to keep her infant safe. Though this was clearly not true given the known risks of preterm formula for babies like M.E., it was enough for Ms. Stills to trust that Defendant Hospital was providing preterm formula in the best interest of her child.

50. Defendants' affirmative acts of fraud and concealment, as averred herein, diverted, prevented, and/or mislead Plaintiff from discovering the medical cause of her child's NEC diagnosis.

The Defendant Manufacturers' False and Misleading Marketing Regarding Cow's Milk-Based Infant Products

51. Abbott and Mead have aggressively marketed their cow's milk-based products as medically endorsed and nutritionally equivalent alternatives to breast milk, including prior to the Injured Infant's birth.

52. Abbott's and Mead's marketing approach includes targeting the parents of preterm infants while they are still in the hospital with messages that the Defendant Manufacturers' cow's milk formulas and fortifiers are necessary for the growth and development of their vulnerable children. Often these tactics implicitly discourage mothers from breastfeeding, which reduces the mother's supply of breast milk. None of the Defendant Manufacturers' marketing materials, including their promotional websites, reference the science showing how significantly their products increase the risk of NEC.

53. For example, upon information and belief, Mead creates information booklets for parents of premature infants to help answer some of their questions and concerns about having a premature

infant in the NICU that it provides to hospitals for dissemination to parents. While Mead's booklets explain feeding options for premature infants, including formula, they do not mention that Mead's premature formula and fortifier products increase the risk of premature infants developing necrotizing enterocolitis. Instead, the booklets advise parents that sometimes a combination of breast milk and formula may be best and that premature infants will be happy and healthy or nourished and healthy regardless of whether they are receiving breast milk or formula.

54. Similarly, upon information and belief, Abbott publishes a pediatric nutrition product guide that is available online for anyone, including parents, to access wherein Abbott advises that "human milk alone does not meet all the nutritional needs of preterm infants" and that the formulations of its products, which are based on decades of research and scientific publications, are "specially designed to meet the nutritional requirements of preterm infants and can be fed with confidence to most of the preterm infants in the NICU." Nowhere in its product guide does Abbott reference that its products increase the risk of necrotizing enterocolitis.

55. Abbott also has a consumer-facing website accessible to anyone online, including parents, that specifically discusses nutrition for premature infants, wherein Abbott tells parents of premature infants that "your baby's nutrient needs are greater than what breast milk alone can provide" and that a "human milk fortifier" may be added to breastmilk to "add[] proteins, vitamins, and minerals to help support a preemie's high nutrition needs for growth and development." Nowhere in its discussion of preterm infant fortifiers or formulas does Abbott state that its products increase the risk of necrotizing enterocolitis or that they pose more of a risk than just providing preterm infants with breast milk only. Nor does Abbott disclose that the "human milk fortifier" is actually a cow's milk based product and not a human milk-based product, which misleads consumers.

56. Upon information and belief, both Mead and Abbott also provide materials and programs to the hospitals and the physicians and medical staff who are treating premature infants about the manufacturers' preterm products. Upon information and belief, these materials represent that the manufacturers' preterm products are safe and necessary for preterm infants. Mead and Abbott rely on the physicians and medical staff to not only use their products in the NICU, but to convey these messages to the parents of premature infants in their care.

57. Undoubtedly aware of the impact of their advertising, the Defendant Manufacturers, along with other formula manufacturers, are willing to spend massive sums to disseminate their message.

58. Recognizing the abuse and dangers of infant formula marketing, in 1981, the World Health Assembly—the decision-making body of the World Health Organization—developed the International Code of Marketing of Breast-milk Substitutes (“the Code”), which required companies to acknowledge the superiority of breast milk, the negative effect on breastfeeding of introducing partial bottle-feeding, and the difficulty of reversing the decision not to breastfeed. The Code also forbade advertising or other forms of promotion of formula to the general public, as well as providing sample products to mothers or members of their families.

59. While Abbott and Mead acknowledge the Code on their websites and claim to support the effort to encourage mothers to breastfeed for as long as possible, this is little more than lip service. Instead, the Defendant Manufacturers' aggressive marketing exploits new parents' darkest fears—that the nutrition they are supplying to their child will not provide the best chance of survival—while wholly failing to warn that their products come with a significantly increased risk of NEC.

60. For example, Abbott's website, on a page titled “Infant Formula Marketing,” states: “We agree with the World Health Organization that breastfeeding provides the best nutrition for babies, and we support its goal to increase breastfeeding. We also recognize that for infants who aren't

breastfed—for medical reasons or otherwise—infant formula is the only appropriate, safe alternative to meet babies’ nutritional needs.” This statement ignores the existence of donor milk, as well as human milk-based formula.

61. Abbott markets and sells multiple products specifically targeting preterm and low-birthweight infants, including Liquid Protein Fortifier, Similac NeoSure, Similac Human Milk Fortifiers, Similac Special Care 20, Similac Special Care 24, Similac Special Care 24 High Protein, and Similac Special Care 30. In advertising these products, Abbott emphasizes the products’ purported ability to assist underdeveloped babies in reaching their growth targets. For example, on the since-edited webpage regarding Similac NeoSure, Abbott noted: “Your premature baby didn’t get her full 9 months in the womb, so her body is working hard to catch up. During her first full year, feed her Similac NeoSure, a nutrient-enriched formula for babies who were born prematurely, and help support her development.” Yet, no mention was made of the accompanying significantly increased risk of NEC. At some point, the website was edited to remove this statement. However, upon information and belief, the statement remained on the website until at least December 2020.

62. Abbott’s website also contains product information and a downloadable guide for each of its products specifically targeting preterm and low-birth-weight infants, including Liquid Protein Fortifier, Similac NeoSure, Similac Human Milk Fortifiers, Similac Special Care 20, Similac Special Care 24, Similac Special Care 24 High Protein, and Similac Special Care 30. None of these pages or guides contain any mention of NEC or that the products specifically increase the risk of NEC. Indeed, a search of Abbott’s website for “necrotizing enterocolitis” returns no hits. Instead, Abbott states that “enteral feeding” – which includes breast milk and donor milk – have been “associated with” things like “[s]pitting up, abdominal distension” or “other signs of

intestinal dysfunction.” This statement is entirely misleading, as it improperly indicates that the risk of things like “spitting up” are the same for premature infants using Abbott’s products and premature infants receiving breast milk or donor milk, equates formula to non-cow’s milk-based feeding options like breast milk and donor milk, fails to mention NEC, and minimizes the risk of its products.

63. Mead markets and sells multiple products specifically targeting premature infants, including Enfamil NeuroPro EnfaCare Infant Formula, Enfamil Premature Infant Formula 24 Cal High Protein, Enfamil Premature Infant Formula 30 Cal with Iron, Enfamil Premature Infant Formula 24 Cal with Iron, Enfamil Premature Infant Formula 20 Cal with Iron, Enfamil 24 Cal Infant Formula, and Enfamil Human Milk Fortifier (acidified liquid and powder). In advertising these products, Mead emphasizes the purported similarities between its formula and breast milk, while failing to include any information about the nutritional deficits and dangers that accompany formula use. For example, the since-edited webpage for Enfamil Enfacare stated: “Premature babies fed Enfamil® formulas during the first year have achieved catch-up growth similar to that of full term, breastfed infants” and noted that Enfamil formulas include “expert-recommended levels of DHA and ARA (important fatty acids found naturally in breast milk) to support brain and eye development.”

64. One Enfamil advertisement, introducing a new product line called Enfamil NeuroPro, is entirely focused on favorably comparing Enfamil’s formula to breast milk, without any mention of the product’s extreme risks. Indeed, the terms “human milk” and “breast milk” are used 13 times in the advertisement, including in such statements as “for decades human milk has inspired the advancements in Enfamil formulas and now through extensive global research, we are taking an even closer look at human milk” and “only Enfamil NeuroPro has a fat blend of MFGM and DHA

previously found only in breast milk.” The webpage for the product has made similar manipulative claims, stating “Enfamil is backed by decades of breast milk research and multiple clinical studies” and it claims that “to create our best formulas, we collaborated on some of the most extensive breast milk studies to date[.]”

65. Mead’s website also contains product information for each of its products specifically targeting preterm and low-birth-weight infants, including Enfamil NeuroPro EnfaCare Infant Formula, Enfamil Premature Infant Formula 24 Cal High Protein, Enfamil Premature Infant Formula 30 Cal with Iron, Enfamil Premature Infant Formula 24 Cal with Iron, Enfamil Premature Infant Formula 20 Cal with Iron, Enfamil 24 Cal Infant Formula, and Enfamil Human Milk Fortifier (acidified liquid and powder). None of these pages contain any mention of NEC or that the products specifically increase the risk of NEC. Indeed, a search of Mead’s website for “necrotizing enterocolitis” returns no hits. Instead, Mead advertises on its website that it “has led the way in developing safe, high-quality, innovative products” – including preterm products – “to help meet the nutritional needs of infants.”

66. Formula manufacturers have long used their relationships with hospitals and the discharge process to encourage parents to substitute formula for breast milk. They offer free or reduced-cost formula to hospitals for use with infants before discharge. And they offer free formula, coupons, and even entire gift baskets to parents before their infants’ discharge from the NICU or hospital.

67. Here, S.P. was discharged from CHOP with the recommendation to continue use of Abbott’s Similac Special Care 24 formula.

68. Through this early targeting, the Defendant Manufacturers create brand loyalty under the guise of a “medical blessing,” in hopes that new parents continue to use formula after they leave the hospital, resulting in increased expense for parents, significantly increased risk for babies, and

increased profit for the Defendant Manufacturers. The Defendant Manufacturers' giveaways and gift baskets send confusing signals to mothers who are simultaneously being encouraged to breastfeed by their healthcare professionals, and they have been shown to negatively impact breastfeeding rates.

69. Further, when the Defendant Manufacturers recognized a shift in the medical community towards an exclusive breast milk-based diet for premature infants, Abbott developed a product called "Similac Human Milk Fortifier," and Mead developed "Enfamil Human Milk Fortifier." These names are misleading in that they suggest that the products are derived from breast milk, when, in fact, they are cow's milk-based products. The packaging appears as:



70. The Defendant Manufacturers have designed powerful misleading marketing campaigns to deceive parents into believing that: (1) cow's milk-based products are safe, including for preterm infants; (2) cow's milk-based products are equal, or even superior, substitutes to breast milk; (3) cow's milk-based products are necessary for proper growth and development of preterm infants; and (4) physicians consider the Defendant Manufacturers' cow's milk-based products to be a first choice. This marketing scheme is employed despite all Defendants knowing of and failing to warn

of the extreme risk of NEC and death that cow's milk-based products pose to preterm infants like the Injured Infant.

71. The Defendant Manufacturers have also designed powerful marketing campaigns to both the general public and health care providers at hospitals like Pennsylvania Hospital. The Defendant Manufacturers know that sales made to hospitals are key drivers of brand loyalty, and thus are a key opportunity to drive better downstream business—*i.e.*, retail purchases by parents after they have left the hospital. On information and belief, the Defendant Manufacturers know that the formula products used in a hospital's NICU are related to getting and keeping the overall hospital contracts. And the Defendant Manufacturers know that, just like any celebrity endorsement, when mothers of newborn infants see medical professionals using a certain brand, the mothers are more likely to continue to purchase that same brand after discharge. The Defendant Manufacturers are thus heavily motivated to ensure that NICU departments are using their products.

72. Abbott and Mead Johnson focus their sales teams and training heavily on hospital NICU departments. They train their sales representatives how to increase the number of babies on their formula, and they emphasize the need to be the dominant formula manufacturer in the NICU so they can own that profitable ground and secure a great return on their substantial investment in NICU formula and other products.

73. To leverage hospitals' NICUs and secure babies in the hospital and at retail, the Manufacturer Defendants pull out all the stops to convince hospitals, including Defendant Hospital, to purchase their products. For example: Abbott and Mead Johnson provide samples of their products to hospitals for free.

74. On information and belief, to get the hospitals on board with supplying their formula for premature infants, Abbott and Mead Johnson work with hospitals to secure contracts that have special pricing discounts if a certain level of the formula-fed babies in the hospital receive just that one manufacturer's products; similar to a restaurant being a Coke or Pepsi restaurant. And notwithstanding the increased risk of the Defendant Manufacturers' products for the hospitals' most fragile patients—the preterm infants—the decision makers at these hospitals seek out these types of contracts to better the hospitals' own bottom lines.

75. On information and belief, Abbott and Mead Johnson also seek promises and/or assurances that the full range of health care providers at the hospitals, including the nurse practitioners and other staff who would pull the infant formula off the shelf, are grabbing the respective company's own formula products to give to the preterm infants. The goal of this tactic was to ensure that the Defendant Manufacturers and key people at the hospital would be sending a shared message that the preterm infant formula products were safe and without risk, even though that is not what the science said.

76. On information and belief, Abbott and Mead Johnson also seek promises and/or assurances that the full range of health care providers at the hospitals, including the nurse practitioners and other staff who would pull the infant formula off the shelf, are grabbing the respective companies' own formula products to give to the preterm infants. The goal of this tactic was to ensure that the Defendant Manufacturers and key people at the hospital would be sending a shared message that the preterm infant formula products were safe and without risk, even though that is not what the science said.

77. On information and belief, prior to M.E.'s birth, Abbott sent sales representatives to Defendant Hospital. Those sales representatives provided information about Abbott's products to

Defendant Hospital's staff via conversations, presentations, and written pamphlets. This information indicated that Abbott's products were safe to give to preterm infants like M.E. Abbott maintains call logs that detail which sales representatives visited the hospitals, which days they visited, and which products they discussed. These sales representatives did not disclose that Abbott's products could cause NEC in preterm infants.

78. On information and belief, prior to M.E.'s birth, Mead Johnson sent sales representatives to Defendant Hospital. Those sales representatives provided information about Mead Johnson's products to Defendant Hospital's staff via conversations, presentations, and written pamphlets. This information indicated that Mead Johnson's products were safe to give to preterm infants like M.E. Mead Johnson maintains call logs that detail which sales representatives visited the hospitals, which days they visited, and which products they discussed. These sales representatives did not disclose that Mead Johnson's products could cause NEC in preterm infants.

79. Mead Johnson and Abbott believed and intended that the misrepresentations that its sales representatives shared with Defendant Hospital would be used to make feeding decisions for preterm infants like M.E.

The Defendant Manufacturers' Inadequate Warnings

80. Although Mead promotes an aggressive marketing campaign designed to convince parents that its cow's milk-based products are safe and necessary for the growth of a premature infant, the product is in fact extremely dangerous for premature infants. Enfamil products significantly increase the chances of a premature infant developing potentially fatal NEC.

81. The Enfamil products Mead markets specifically for premature infants are commercially available at retail locations and online. No prescription is necessary.

82. Despite knowing of the risk of NEC, the packaging of Mead's products does not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated

with Mead's products, or of the magnitude of this increased risk. Mead likewise did not provide instructions or guidance for how to avoid NEC.

83. Mead cites no medical literature or research to guide the use of its products.

84. Despite knowing of the risk of NEC, Mead did not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with its products, or of the magnitude of this increased risk. Mead likewise did not provide instructions or guidance for how to avoid NEC.

85. Mead deceived the public, parents, physicians, other medical professionals, and medical staff into believing that Enfamil products were a safe and necessary alternative, supplement and/or substitute to breast milk.

86. Mead Johnson failed to provide, and continues to fail to provide, a full accounting of the risk of NEC as documented, by underrepresenting and misrepresenting the risk to the public and the medical community.

87. Despite knowing that its products were being fed to premature infants, often without the parents' informed consent, Mead failed to require or recommend that medical professionals inform parents of the significant risk of NEC or to require that parental consent be obtained prior to the products being fed to their babies. Like Mead, Abbott promotes an aggressive marketing campaign designed to make parents believe that its products are safe and necessary for the growth of premature infants, despite the products in fact being extremely dangerous for premature infants. Abbott's products significantly increase the chances of a premature infant getting potentially fatal NEC.

88. The products Abbott markets specifically for premature infants are available at retail locations and online. No prescription is necessary.

89. Despite knowing of the risk of NEC, Abbott did not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with its products, or of the magnitude of this increased risk. Abbott likewise did not provide instructions or guidance for how to avoid NEC.

90. Abbott deceived the public, parents, physicians, other medical professionals, and medical staff into believing that its products were a safe and necessary alternative, supplement and/or substitute to breast milk.

91. Despite knowing of studies documenting an increased risk of NEC from its products, Abbott did not act to make parents or the medical community aware of those risks, and instead took steps to conceal or prevent those risks from becoming public. Despite knowing that its products were being fed to premature infants, often without the parents' informed consent, Abbott failed to require or recommend that medical professionals inform parents of the significant risk of NEC or to require that parental consent be obtained prior to the products being fed to their babies.

Penn Medicine's Failure to Warn

92. On information and belief, Penn Medicine, which operates Pennsylvania Hospital, was aware of the significantly increased risk of NEC and death associated with providing Abbott's and Mead's cow's milk-based products to its premature infant patients. It knew or should have known that feeding these cow's milk-based products can cause NEC in premature infants who otherwise would not have developed this devastating condition. It also knew or should have known that human milk decreases the risk of NEC for premature infants. However, instead of warning of the dangers, or supplying human milk-based feeding products to preterm infants like the Injured Infant, Penn Medicine has continued to source, distribute, and supply the Defendant Manufacturers' products in its hospitals without any adequate warning.

93. To that end, Penn Medicine has participated in studies designed to increase the use of donor milk while, at the same time, reducing formula feeding in neonates. The University of Pennsylvania School of Nursing, an affiliate of Penn Medicine, has conducted extensive research into the risks associated with feeding formula to premature infants. It recently partnered with the National Institute of Nursing Research to publish clinical determinations based on its experience “changing hospital systems and influencing policy,” and its findings were unequivocal:

This is what we know about the science of human milk: it reduces the risk of necrotizing enterocolitis, reduces the risk of infection, [and] creates greater enteral feed tolerance and more rapid weaning from intravenous nutrition. . . .

94. Other Penn Medicine research has similarly concluded that “[h]uman milk decreases the incidence and severity of . . . necrotizing enterocolitis (NEC).”

95. Given it was known that human milk decreases the incidence and severity of NEC, it was also known or should have been known that cows milk-based formula increases the incidence and severity of NEC.

96. Penn Medicine also purports to adhere to the tenets of the “Baby Friendly Hospital Initiative,” which seeks to increase rates of breastfeeding initiation, exclusivity, and diet duration. The “Baby Friendly Hospital Initiative” specifically targets a reduction in the rates of NEC in preterm infants by encouraging implementation of exclusive breast milk diets among new mothers. Although Pennsylvania Hospital has maintained its “Baby Friendly” designation for years, it has not eliminated or restricted the use of formula or fortifier for preterm infants in its hospitals.

97. Given it was known since at least the early 2000s, and as far back as the 1990s, that human milk decreases the incidence and severity of NEC, it was also known or should have been known that cows milk-based formula increases the incidence and severity of NEC.

98. Penn Medicine also purports to adhere to the tenets of the “Baby Friendly Hospital Initiative,” which seeks to increase rates of breastfeeding initiation, exclusivity, and diet duration.

The “Baby Friendly Hospital Initiative” specifically targets a reduction in the rates of NEC in preterm infants by encouraging implementation of exclusive breast milk diets among new mothers. Although Pennsylvania Hospital has maintained its “Baby Friendly” designation for years, it has not eliminated or restricted the use of formula or fortifier for preterm infants in its hospitals.

99. Finally, medical providers and staff at Penn Medicine have acknowledged the risks associated with providing the Defendant Manufacturers’ cow’s milk-based products to premature infant patients instead of breast milk-based nutrition. In an internal newsletter from 2012 touting donor milk programs, Penn Medicine acknowledged the benefits of a human milk-based diet, quoting a staff lactation consultant:

Donor milk is not inexpensive. It costs about \$4.25 per ounce, but the return on investment is huge. “Preemies given mother’s milk get discharged three to four days sooner and also have a six to 10 times lower risk of getting a gastrointestinal complication called necrotizing enterocolitis,” Carpenter said, adding that the infection can cost up to \$250,000 to treat. The average cost to provide a preemie with donor milk: \$125.

100. These statements demonstrate that Penn Medicine knew or should have known of the high increased risk of NEC for premature infants posed by the Defendant Manufacturers’ products.

101. Although Penn Medicine knew or should have known of the serious danger of the Defendant Manufacturers’ products, it has continued to purchase, supply, and distribute these products to preterm infants without providing full and adequate warnings of the attendant risks to parents, healthcare professionals, and other medical staff at its relevant facilities. As a result, the Injured Infant was fed the Defendant Manufacturers’ cow’s milk-based products at Pennsylvania Hospital, causing their injuries. This occurred even though hospitals across the country, including Pennsylvania Hospital, warn and obtain consent from parents before providing other safer forms of nutrition, such as donor breast milk.

102. Penn Medicine's failure to warn of the risks posed by the Defendant Manufacturers' products is entrenched (and compounded) by the financial benefits it accrues from its relationships with the Defendant Manufacturers. On information and belief, it has received the Defendant Manufacturers' cow's milk-based products for free and/or at a significant discount, and has granted their sales representatives access to its healthcare professionals and medical staff. These sales representatives have provided deceptive information that Penn Medicine reasonably knew or should have known would ultimately reach parents through those staff. This arrangement dovetails with the Defendant Manufacturers' own marketing strategies" and use of salespersons.

Safer Alternative Designs

103. The Defendant Manufacturers' cow's milk-based products made specifically for premature infants are unreasonably unsafe for those infants. The Defendant Manufacturers could have used pasteurized breast milk instead of cow's milk in their products, which would have produced a safer product.

104. Prolacta Bioscience manufactures and sells breast milk-based feeding products, specifically designed for preterm infants, which contain no cow's milk. This alternative design provides all the necessary nutrition for growth and development that cow's milk-based products provide, without the same unreasonably dangerous and deadly effects.

105. On information and belief, Abbott and Mead were aware of the significantly increased risk of NEC and death associated with their cow's milk-based products, and instead of warning of the dangers, or removing them altogether, Abbott and Mead have continued to use cow's milk as the foundation of their products.

CAUSES OF ACTION
COUNT I: STRICT LIABILITY FOR DESIGN DEFECT
(Against Abbott and Mead)

106. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

107. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to manufacture, sell, and distribute their products in a manner that was not unreasonably dangerous.

108. Abbott and Mead also owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to manufacture, sell, and distribute their products in a manner that was merchantable and reasonably suited for their intended use.

109. Abbott and Mead knew that their products would be used to feed premature infants like the Injured Infant and knew (or reasonably should have known) that use of their cow's milk-based products significantly increased the risk of NEC, serious injury, and death, and that such use was therefore unreasonably dangerous to premature infants, not reasonably suited for the use intended, not merchantable, and had risks that exceeded a reasonable buyer's expectations. Nonetheless, they continued to sell and market their defective products as appropriate for premature infants.

110. The Injured Infant ingested Abbott and/or Mead's unreasonably dangerous cow's milk-based products. The risks of feeding those products to the Injured Infant outweighed the benefits. An ordinary consumer would not expect those products to carry a significant risk of serious injury and death from NEC.

111. Abbott and Mead knew (or reasonably should have known) that breast milk-based nutrition did not carry the same risks of NEC, serious injury, and death that their products do.

112. Abbott's and Mead's products contained cow's milk at the time they left the manufacturing

facility.

113. Abbott and Mead did not develop a human-milk based product that was safer for premature infants and did not reformulate their products to reduce the risk of NEC, serious injury, and death, even though doing so was economically and technologically feasible and even though pasteurized breast milk was an available alternative.

114. Abbott's and/or Mead's products were fed to the Injured Infant, which caused and/or increased the risk of their NEC and injuries.

115. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational

limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;

- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT II: STRICT LIABILITY FOR FAILURE TO WARN
(Against Abbott and Mead)**

116. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

117. Abbott and Mead, as the manufacturers and/or sellers of the infant products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide adequate warnings or instructions about the dangers and risks associated with the use of their products with preterm infants, specifically including but not limited to the risk of NEC, serious injury, and death.

118. Abbott's and Mead's duty to warn is part of their general duty to design, manufacture, and sell their infant products in a manner that is reasonably safe for their foreseeable uses. By designing their products with cow's milk-based ingredients, Abbott and Mead undertook a duty to warn of the unreasonable risk of harm posed by those ingredients, specifically including the significantly increased risk of NEC, severe injury, and death. The failure to warn makes the products at issue in this litigation unreasonably dangerous.

119. Specifically, Abbott and Mead breached their duty to warn of the foreseeable risks of the infant products at issue in this litigation because they knew or should have known that their cow's milk-based premature infant products would be fed to premature infants like the Injured

Infant, and that their products might cause the Injured Infant to develop NEC, severe injury, or death, yet they failed to provide adequate warnings of those risks. Among other risks, the Defendant Manufacturers:

- a. Failed to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death for the Injured Infant; and/or
- b. Failed to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or
- c. Inserted warnings and instructions on their products that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC and death; and/or
- d. "Black box"-type warning that their cow's milk-based products are known to significantly increase the risk of NEC and death when compared to breast milk in premature infant; and/or
- e. Failed to disclose well-researched and well-established studies that linked cow's milk-based products to NEC and death in premature infants; and/or
- f. Failed to insert a warning or instruction to healthcare professionals and other medical staff in the hospital that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risks; and/or
- g. Failed to provide a warning in a method reasonably calculated or expected to reach the parents of newborns, like the Plaintiff Parent; and/or
- h. Failed to provide statistical evidence showing the magnitude of increased risk of

NEC in premature infants associated with cow's milk-based products.

120. Abbott's and Mead's products contained cow's milk at the time they left the manufacturing facility.

121. As a direct and proximate result of the inadequacy of the warnings and the pervasive marketing campaigns suggesting the safety and necessity of the Defendant Manufacturers' products, the Injured Infant were fed cow's milk-based products, which caused and/or increased risk of their developing NEC.

122. The unwarned-of risks are not of a kind that an ordinary consumer would expect. Had physicians and medical staff known of the extreme risk associated with feeding premature infants cow's milk-based formula, they would not have fed the Injured Infant those products. Had the Plaintiff Parent known of the significant risks of feeding the Injured Infant cow's milk-based formula, they would not have allowed such products to be fed to the Injured Infant.

123. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue,

and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;

- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendants Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT III: NEGLIGENCE
(Against Abbott and Mead)**

124. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

125. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to exercise reasonable care to design, test, manufacture, inspect, and distribute a product free of unreasonable risk of harm to users, when such products are used in their intended manner and for their intended purpose.

126. At all times relevant to this action, the Injured Infant's healthcare professionals and medical staff used the products at issue in their intended manner and for their intended purpose.

127. Abbott and Mead, directly or indirectly, negligently, and/or defectively made, created, manufactured, designed, assembled, tested, marketed, sold, and/or distributed the cow's milk-based infant products at issue in this litigation and thereby breached their duty to the general public and the Plaintiff Parent.

128. Specifically, although Abbott and Mead knew or reasonably should have known at the time of production that their cow's milk-based infant products significantly increased the risk of NEC, serious injury, and death, they failed to act in a reasonably prudent manner and breached their duty by:

- a. Failing to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death for the Injured Infant; and/or
- b. Failing to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or
- c. Inserting warnings and instructions that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC and death; and/or
- d. Failing to insert a large and prominent "black box"-type warning that their cow's milk-based products are known to significantly increase the risk of NEC and death when compared to breast milk in premature infants; and/or
- e. Failing to provide well-researched and well-established studies that linked cow's milk-based products to NEC and death in premature infants; and/or
- f. Failing to insert a warning or instruction to healthcare professionals and other medical staff in the hospital that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risks; and/or
- g. Failing to provide a warning in a method reasonably calculated/expected to reach the parents of newborns, like the Plaintiff Parent; and/or

- h. Failing to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products.

129. In addition, although Abbott and Mead knew or reasonably should have known at the time of production that their cow's milk-based products significantly increased the risk of NEC, serious injury, and death, they failed to act in a reasonably prudent manner and breached their duty by failing to perform the necessary process of data collection, detection, assessment, monitoring, prevention, and reporting or disclosure of adverse outcomes in infants who ingest their products.

130. As a direct and proximate result of the Defendant Manufacturers' failure to act in a reasonably prudent manner and their breach of duty, the Injured Infant was fed cow's milk-based products, which caused and/or increased the risk of their developing NEC.

131. Had Abbott and Mead satisfied their duties to the consuming public in general, the Injured Infant would not have been exposed to their unreasonably dangerous cow's milk-based products.

132. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs

related to medical or mental health treatment which have or may be recommended;

- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendants Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT IV: INTENTIONAL MISREPRESENTATION
(Against Abbott and Mead)**

133. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

134. At all times relevant to this action, the Injured Infant consumed the Defendant Manufacturers' products in their intended manner and for their intended purpose.

135. Abbott and Mead, as the manufacturers and/or sellers of the infant products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide truthful, accurate, fulsome information about the risks and benefits of using their products when used in the intended manner and for the intended purpose.

136. Abbott and Mead breached their duty through misrepresentations made to consumers in their advertising and promotional materials, as described in previous paragraphs and incorporated herein, each of whom were foreseeable and intended recipients of this information.

137. Specifically, upon information and belief, Abbott and Mead made the following false statements of material fact on an ongoing and repeated basis to the public, including patient consumers, and parents like Plaintiff Parent and prior to the time the Injured Infant was fed their

products:

- a. That their cow's milk-based products were safe and beneficial for premature infants when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or
- b. That their cow's milk-based products were necessary to the growth and nutrition of premature infants, when they knew or should have known that their products were not necessary to achieve adequate growth; and/or
- c. That their products have no serious side effects, when they knew or should have known the contrary to be true; and/or
- d. That cow's milk-based products were safe for premature infants; and/or
- e. That cow's milk-based products were necessary for optimum growth; and/or
- f. That cow's milk-based products were similar or equivalent to breast milk; and/or
- g. That their products were safe and more like breast milk than other infant products and that they had removed the harmful ingredients of cow's milk when, in fact, the cow's milk in their products was still capable of causing NEC, serious injury, and death; and/or
- h. That their products were safe for and provided better nutrition and growth to premature infants than donor milk, a non-cow's milk-based alternative to breast milk; and/or
- i. That their products can fed with confidence to most of the preterm infants in the NICU and/or that premature infants would be happy and health or nourished and health on their products; and/or
- j. That their products were based on up-to-date science, which made them safe for

premature infants; and/or

- k. Omitting the material fact that their products significantly increased the risk of NEC in premature infants, including omitting this material fact from their publicly available product information, marketing materials, and websites..

138. Abbott and Mead had actual knowledge, or, at a minimum, a reckless indifference, to whether the aforementioned misrepresentations were false.

139. In addition to the above, Abbott and Mead, upon information and belief, also made the following false statements of material fact to Plaintiff Parent:

- a. Omitting from coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent that their products significantly increased the risk of NEC in premature infants; and/or
- b. Omitting from the packaging and labeling of their products provided to Injured Infant that their products significantly increased the risk of NEC in premature infants; and/or
- c. Representing that their cow's milk-based products were safe and beneficial for premature infants on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or
- d. Representing that their cow's milk-based products were safe and beneficial for premature infants on the packaging and labeling of their products provided to Injured Infant when they knew or should have known that their products were

unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or

- e. Representing that their cow's milk-based products were necessary to the growth and nutrition of premature infants on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent when they knew or should have known that their products were not necessary to achieve adequate growth; and/or
- f. Representing that their cow's milk-based products were necessary to the growth and nutrition of premature infants on the packaging and labeling of their products provided to Injured Infant when they knew or should have known that their products were not necessary to achieve adequate growth; and/or
- g. Representing that their cow's milk-based products were similar or equivalent to breast milk on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent; and/or
- h. Representing that their cow's milk-based products were similar or equivalent to breast milk on the packaging and labeling of their products provided to Injured Infant; and/or
- i. Representing that their cow's milk-based products could be fed with confidence to premature infants and/or that premature infants would be healthy regardless of whether they were fed their cow's milk-based products or breast milk on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent; and/or

- j. Representing that their cow's milk-based products could be fed with confidence to premature infants and/or that premature infants would be healthy regardless of whether they were fed their cow's milk-based products or breast milk on the packaging and labeling of their products provided to Injured Infant; and/or
- k. Representing that their cow's milk-based products have no serious side effects on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent when they knew or should have known the contrary to be true; and/or
- l. Representing that their cow's milk-based products have no serious side effects on the packaging and labeling of their products provided to Injured Infant when they knew or should have known the contrary to be true; and/or
- m. Representing that their cow's milk-based products were similar or equivalent to breast milk on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent when they knew or should have known the contrary to be true; and/or
- n. Representing that their cow's milk-based products were similar or equivalent to breast milk on the packaging and labeling of their products provided to Injured Infant when they knew or should have known the contrary to be true; and/or
- o. Representing that their cow's milk-based products were safe for premature infants on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent; and/or
- p. Representing that their cow's milk-based products were safe for premature infants on the packaging and labeling of their products provided to Injured Infant; and/or

- q. Representing that their cow's milk-based products were necessary for optimum growth on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent; and/or
- r. Representing that their cow's milk-based products were necessary for optimum growth on the packaging and labeling of their products provided to Injured Infant; and/or
- s. Representing that their products were based on up-to-date science, which made them safe for premature infants on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent; and/or
- t. Representing that their products were based on up-to-date science, which made them safe for premature infants on the packaging and labeling of their products provided to Injured Infant.

140. The Plaintiff Parent was not aware that these misrepresentations were false and justifiably relied on them. The Defendant Manufacturers' misrepresentations induced the Plaintiff Parent to allow their children to be fed Abbott's and Mead's infant products, in reliance on all the messaging they received about formula feeding, including, directly or indirectly, the Defendant Manufacturers' messaging. Had Abbott and Mead not committed these intentional misrepresentations, the Injured Infant would not have been exposed to the Defendant Manufacturers' unreasonably dangerous cow's milk-based products.

141. As a direct and proximate result, Abbott's and Mead's products were fed to the Injured Infant, which caused and/or increased risk of their developing NEC and subsequent injuries.

142. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss

of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT V: NEGLIGENT MISREPRESENTATIONS
(Against Abbott and Mead)**

143. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

144. At all times relevant to this action, the Injured Infant consumed the products at issue in

their intended manner and for their intended purpose.

145. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide truthful, accurate, and complete information about the risks and benefits of using their products when used in the intended manner and for the intended purpose.

146. In the course of their business, Abbott and Mead breached their duty through misrepresentations made to consumers in their advertising and promotional materials, as described in previous paragraphs and incorporated herein, each of whom were foreseeable recipients of this information.

147. Specifically, upon information and belief, Abbott and Mead made the following false statements of material fact on an ongoing and repeated basis to the public, including consumers, and parents like Plaintiff Parent and prior to the time the Injured Infant was fed their products:

- a. That their cow's milk-based products were safe and beneficial for premature infants when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or
- b. That their cow's milk-based products were necessary to the growth and nutrition of premature infants, when they knew or should have known that their products were not necessary to achieve adequate growth; and/or
- c. That their products have no serious side effects, when they knew or should have known the contrary to be true; and/or
- d. That cow's milk-based products were safe for premature infants; and/or
- e. That cow's milk-based products were necessary for optimum growth; and/or
- f. That cow's milk-based products were similar or equivalent to breast milk; and/or

- g. That their products were safe and more like breast milk than other infant products and that they had removed the harmful ingredients of cow's milk when, in fact, the cow's milk in their products was still capable of causing NEC, serious injury, and death; and/or
- h. That their products were safe for and provided better nutrition and growth to premature infants than donor milk, a non-cow's milk-based alternative to breast milk; and/or
- i. That their products can be fed with confidence to most of the preterm infants in the NICU and/or that premature infants would be happy and healthy or nourished and healthy on their products; and/or
- j. That their products were based on up-to-date science, which made them safe for premature infants; and/or
- k. Omitting the material fact that their products significantly increased the risk of NEC in premature infants, including omitting this material fact from their publicly available product information, marketing materials, and websites.

148. In addition to the above, Abbott and Mead, upon information and belief, also made the following false statements of material fact to Plaintiff Parent.

- a. Omitting from coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent that their products significantly increased the risk of NEC in premature infants; and/or
- b. Omitting from the packaging and labeling of their products provided to Injured Infant that their products significantly increased the risk of NEC in premature infants; and/or

- c. Representing that their cow's milk-based products were safe and beneficial for premature infants on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or
- d. Representing that their cow's milk-based products were safe and beneficial for premature infants on the packaging and labeling of their products provided to Injured Infant when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or
- e. Representing that their cow's milk-based products were necessary to the growth and nutrition of premature infants on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent when they knew or should have known that their products were not necessary to achieve adequate growth; and/or
- f. Representing that their cow's milk-based products were necessary to the growth and nutrition of premature infants on the packaging and labeling of their products provided to Injured Infant when they knew or should have known that their products were not necessary to achieve adequate growth; and/or
- g. Representing that their cow's milk-based products were similar or equivalent to breast milk on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent; and/or

- h. Representing that their cow's milk-based products were similar or equivalent to breast milk on the packaging and labeling of their products provided to Injured Infant; and/or
- i. Representing that their cow's milk-based products could be fed with confidence to premature infants and/or that premature infants would be healthy regardless of whether they were fed their cow's milk-based products or breast milk on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent; and/or
- j. Representing that their cow's milk-based products could be fed with confidence to premature infants and/or that premature infants would be healthy regardless of whether they were fed their cow's milk-based products or breast milk on the packaging and labeling of their products provided to Injured Infant; and/or
- k. Representing that their cow's milk-based products have no serious side effects on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent when they knew or should have known the contrary to be true; and/or
- l. Representing that their cow's milk-based products have no serious side effects on the packaging and labeling of their products provided to Injured Infant when they knew or should have known the contrary to be true; and/or
- m. Representing that their cow's milk-based products were similar or equivalent to breast milk on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent when they knew or should have known the contrary to be true; and/or

- n. Representing that their cow's milk-based products were similar or equivalent to breast milk on the packaging and labeling of their products provided to Injured Infant when they knew or should have known the contrary to be true; and/or
- o. Representing that their cow's milk-based products were safe for premature infants on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent; and/or
- p. Representing that their cow's milk-based products were safe for premature infants on the packaging and labeling of their products provided to Injured Infant; and/or
- q. Representing that their cow's milk-based products were necessary for optimum growth on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent; and/or
- r. Representing that their cow's milk-based products were necessary for optimum growth on the packaging and labeling of their products provided to Injured Infant; and/or
- s. Representing that their products were based on up-to-date science, which made them safe for premature infants on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent; and/or
- t. Representing that their products were based on up-to-date science, which made them safe for premature infants on the packaging and labeling of their products provided to Injured Infant.

149. Abbott and Mead were negligent or careless in not determining those representations to be false.

150. The Defendant Manufacturers' misrepresentations induced, and were intended to induce, the Plaintiff Parent to allow their child to be fed Abbott's and Mead's infant products, in justifiable reliance on all the messaging they received about formula feeding, including, directly or indirectly, the Defendant Manufacturers' messaging. Had Abbott and Mead not committed these negligent misrepresentations, the Injured Infant would not have been exposed to their unreasonably dangerous cow's milk-based products.

151. As a direct and proximate result, Abbott's and Mead's products were fed to the Injured Infant, which caused and/or increased of their developing NEC and subsequent injuries.

152. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or

malicious conduct, as permitted by law;

e. For interest as permitted by law;

f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and

g. For such other and further relief as the Court deems proper.

**COUNT VI: FAILURE TO WARN
(Against Penn Medicine and Pennsylvania Hospital)**

153. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

154. Penn Medicine and Pennsylvania Hospital as purchaser, supplier, and/or distributor of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to purchase, supply, and distribute products that were free of unreasonable risk of harm when used in their intended manner and for their intended purpose, and/or to formulate, adopt, and enforce adequate rules and policies for the same.

155. At all times relevant to this action, the Injured Infant used the cow's milk-based products purchased, supplied, and/or distributed by Penn Medicine and Pennsylvania Hospital in their intended manner and for their intended purpose.

156. Penn Medicine and Pennsylvania Hospital employed or contracted with the healthcare professionals and medical staff at Pennsylvania Hospital, managing these individuals during their treatment of the Injured Infant.

157. Penn Medicine and Pennsylvania Hospital negligently, outrageously, and recklessly supplied and distributed the Defendant Manufacturers' milk-based infant feeding products to these healthcare professionals and medical staff for use on premature infants, including the Injured Infant.

158. Moreover, at all relevant times, Penn Medicine and Pennsylvania Hospital knowingly authorized the Defendant Manufacturers' sales representatives to market, advertise, distribute, and/or sell their products at Pennsylvania Hospital. The Defendant Manufacturers' sales representatives were encouraged to interact with Pennsylvania Hospital's healthcare professionals and medical staff. These interactions provided the Defendant Manufacturers' sales representatives an opportunity to co-opt Pennsylvania Hospital's healthcare professionals and medical staff into assisting with the marketing, distribution, and/or sale of the Defendant Manufacturers' unreasonably dangerous products to consumers, such as the Plaintiff Parent.

159. Penn Medicine and Pennsylvania also knowingly, and intentionally, allowed the Defendant Manufacturers' sales representatives to routinely misrepresent the risks and benefits of Defendants' products to Pennsylvania Hospital's healthcare professionals and medical staff, including the misrepresentation that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

160. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known at the time that they acquired, distributed, and supplied the Defendant Manufacturers' cow's milk-based infant products that these products significantly increased the risk of NEC, serious injury, and death.

161. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, outrageously, and recklessly, and breached its duty by:

- a. Failing to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in those babies; and/or
- b. Failing to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or

- c. Failing to warn or instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risk; and/or
- d. Failing to provide its healthcare professionals and medical staff with the well-researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or
- e. Failing to provide a warning in a method reasonably calculated/expected to reach the parents of newborns; and/or
- f. Failing to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products; and/or
- g. Failing to prevent the Defendant Manufacturers' sales representatives from misrepresenting to Pennsylvania Hospital's healthcare professionals and medical staff that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

162. Reasonable hospitals under the same or similar circumstances would have warned of the above risks, would have instructed their healthcare professionals and medical staff—as well as patients—on the safe use of the Defendant Manufacturers' products, and would have restricted the ability of the Defendant Manufacturers' sales representatives to market the Defendant Manufacturers' unreasonably dangerous products without adequate warning.

163. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that its medical professionals and the parents of premature infants, including the Plaintiff Parent, would not have realized the risks associated with feeding cow's milk-based formula to premature infants.

164. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its duty to warn its medical providers and patients about the Defendant Manufacturers' unreasonably dangerous products, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

165. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital's failure to warn of the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

166. As a further direct and proximate result of Penn Medicine and Pennsylvania Hospital's failure to warn of the Defendant Manufacturers' unreasonably dangerous products, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against Penn Medicine and Pennsylvania Hospital, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of Penn Medicine's conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit

resulting from Penn Medicine and Pennsylvania Hospital's oppressive, outrageous, reckless, and/or malicious conduct, as permitted by law;

- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT VII: CORPORATE LIABILITY OF HEALTH-CARE PROVIDER
(Against Penn Medicine and Pennsylvania Hospital)**

167. Plaintiff incorporates by references each of the preceding paragraphs as if fully set forth herein.

168. At all relevant times, Penn Medicine and Pennsylvania Hospital owed a duty of care to the Injured Infant to ensure their safety and well-being while the Injured Infant was under the care of Pennsylvania Hospital staff. Specifically, Penn Medicine and Pennsylvania Hospital had a duty to the Injured Infant to formulate, adopt, and enforce adequate rules and policies to ensure quality care for the Injured Infant. Further, Penn Medicine and Pennsylvania Hospital owed a duty to the Injured Infant to oversee its healthcare professionals and medical staff that provided patient care to the Injured Infant.

169. Penn Medicine and Pennsylvania Hospital owed a duty to its patients, and the Injured Infant in particular, to formulate, adopt, and enforce adequate rules and policies for the purchase, supply, distribution, and use of products that were free of unreasonable risk of harm when used in their intended manner and for their intended purpose and ensured quality care for the Injured Infant.

170. At all times relevant to this action, the Injured Infant used the cow's milk-based products purchased, supplied, and/or distributed by Penn Medicine and Pennsylvania Hospital in their intended manner and for their intended purpose.

171. Moreover, at all relevant times, Penn Medicine and Pennsylvania Hospital knowingly authorized the Defendant Manufacturers' sales representatives to market, advertise, distribute, and/or sell their products at Pennsylvania Hospital. The Defendant Manufacturers' sales representatives were encouraged to interact with Pennsylvania Hospital's healthcare professionals and medical staff. These interactions provided the Defendant Manufacturers' sales representatives an opportunity to co-opt Pennsylvania Hospital's healthcare professionals and medical staff into assisting with the marketing, distribution, and/or sale of the Defendant Manufacturers' unreasonably dangerous products.

172. Penn Medicine and Pennsylvania Hospital also knowingly allowed the Defendant Manufacturers' sales representatives to routinely misrepresent the risks and benefits of Defendants' products to Pennsylvania Hospital's healthcare professionals and medical staff, including the misrepresentation that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

173. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known at the time that it formulated, adopted, and enforced its rules for the acquisition, distribution, and supply of the Defendant Manufacturers' cow's milk-based infant products, including the access afforded the Defendant Manufacturer's sales representatives, that these products significantly increased the risk of NEC, serious injury, and death for premature infants.

174. Since prior to 2000, Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that premature babies are increased risk for NEC.

175. Since prior to 2000, Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that NEC increases the risk of permanent injury and death.

176. Since 2000, Penn Medicine and Pennsylvania Hospital knew or reasonably should have

known prior to that human milk (mother's milk) was safest and best for premature infants.

177. Since 2000, Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that human milk (mother's milk) decreased the risk of NEC, serious injury, and death for premature infants.

178. By no later than 2012, Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that donor human milk decreased the risk of NEC, serious injury, and death for premature infants.

179. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that its medical professionals and the parents of premature infants, including the Plaintiff Parent, would not have realized the risks associated with feeding cow's milk-based formula to premature infants.

180. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, outrageously, and recklessly, and breached its duty by:

- a. Failing to formulate, adopt, and enforce adequate rules and policies that would have required human milk (mother's milk and/or donor milk) to be recommended to premature babies; and/or
- b. Failing to formulate, adopt, and enforce adequate rules and policies that would have restricted or prevented the use of cow's milk-based products for feeding premature babies; and/or
- c. Failing to formulate, adopt, and enforce adequate rules and policies that informed the Plaintiff Parent that human milk (mother's milk and/or donor milk) significantly decrease the risk of NEC, severe injury, and death in premature babies, like the Injured Infant; and/or
- d. Failing to formulate, adopt, and enforce adequate rules and policies that warned the

Plaintiff Parent that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in premature babies, like the Injured Infant; and/or

- e. Failing to formulate, adopt, and enforce adequate rules and policies that discussed the risks of cow's milk-based products significantly increasing the risk of NEC, severe injury, and death in premature babies, like the Injured Infant; and/or
- f. Failing to formulate, adopt, and enforce adequate rules and policies that warned its healthcare professionals and medical staff that cow's milk-based products are unsafe and/or contraindicated for premature babies like the Injured Infant; and/or
- g. Failing to formulate, adopt, and enforce adequate rules and policies to instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risk; and/or
- h. Failing to formulate, adopt, and enforce adequate rules and policies to provide its healthcare professionals and medical staff with the well-researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or
- i. Failing to formulate, adopt, and enforce adequate rules and policies to ensure a warning in a method reasonably calculated/expected to reach the parents of premature newborns, like the Plaintiff Parent; and/or
- j. Failing to formulate, adopt, and enforce adequate rules and policies to prevent the Defendant Manufacturers' sales representative from misrepresenting to Pennsylvania Hospital's healthcare professionals and medical staff that premature

babies would not grow adequately with human milk and human milk products and/or that use of donor milk was not advised for premature infants; and/or

- k. Failing to establish a donor milk program that was sufficient to meet the needs of the premature babies, like the Injured Infant.
- l. Failing to formulate, adopt, and enforce adequate rules and policies regarding the feeding of premature infants leaving it to the discretion of the medical team and parent without a discussion of risks and benefits.
- m. Allowing parental preference to be the standard for feeding premature infants;
- n. Failing to follow the American Academy of Pediatrics recommendations relating to feeding premature infants;
- o. Failing to follow the American Academy of Pediatrics recommendations to use donor milk if mother's milk was unavailable instead of cow's milk-based products;
- p. Failing to recommend donor milk if mother's milk was unavailable by no later than 2012; and
- q. Failing to transfer to a hospital by no later than 2012 where donor milk was available if there was no donor milk available.

181. A reasonable hospital under the same or similar circumstances would have formulated, adopted, and enforced adequate policies, and rules to restrict the feeding of cow's milk-based products to premature babies, including developing an adequate donor milk program, instructing its healthcare professionals and medical staff on the safe use of Defendants Manufacturers' cow's milk-based products, and restricting the marketing of the Defendant Manufacturers' unreasonably dangerous products to its healthcare professionals, medical staff, and parents of premature infants under its care.

182. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its duty to formulate, adopt, and enforce adequate rules and policies to ensure the quality care of its patients, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

183. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital failure to formulate and enforce adequate policies and rules related to the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

184. As a further direct and proximate result of Penn Medicine and Pennsylvania Hospital negligent, reckless, and outrageous conduct the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

185. In the alternative, Penn Medicine and Pennsylvania Hospital owed a duty to its patients, and the Injured Infant in particular, to oversee the practicing healthcare professionals and medical staff that provided the products at issue to infants under Pennsylvania Hospital's care, including the Injured Infant.

186. Penn Medicine and Pennsylvania Hospital employed or contracted with the healthcare professionals and medical staff at Pennsylvania Hospital and was responsible for overseeing those individuals during their treatment of the Injured Infant.

187. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, recklessly, and outrageously breached its duty by:

- a. Failing to oversee its healthcare professionals and medical staff on their use of

cow's milk-based products for feeding premature babies; and/or

- b. Failing to warn or instruct its healthcare professionals and medical staff that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in those babies; and/or
- c. Failing to warn or instruct its healthcare professionals and medical staff that cow's milk-based products are unsafe and/or contraindicated for premature babies like the Injured Infant; and/or
- d. Failing to oversee its healthcare professionals and medical staff to restrict their feeding of cow's milk-based products to premature babies; and/or
- e. Failing to warn or instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risk; and/or
- f. Failing to provide its healthcare professionals and medical staff with the well-researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or
- g. Failing to provide its healthcare professionals and medical staff with warnings about the dangers of the Defendants' Manufacturers products in a method reasonably calculated/expected to reach the parents of newborns; and/or
- h. Failing to provide statistical evidence to its healthcare professionals and medical staff showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products; and/or
- i. Failing to oversee its healthcare professionals and medical staff to ensure that the

Defendant Manufacturers' sales representatives' misrepresentations that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants had not influenced the use and/or misuse of the Defendant Manufacturers' products.

188. A reasonable hospital under the same or similar circumstances would have warned of the above risks, would have instructed its healthcare professionals and medical staff on the safe use of the Defendant Manufacturers' products, and would have restricted the ability of the Defendant Manufacturers' sales representatives to market the Defendant Manufacturers' unreasonably dangerous products without adequate warning.

189. A reasonable hospital under the same or similar circumstances would have overseen and managed its healthcare professionals and medical staff to ensure that they received proper training and updating on the risks associated with feeding cow's milk-based formula to premature infants.

190. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its duty to oversee its healthcare professionals and medical staff who provide patient care, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

191. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital's failure to oversee its healthcare professionals and medical staff on the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

192. As a further direct and proximate result of Penn Medicine and Pennsylvania Hospital's negligent and reckless conduct, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's

injuries.

WHEREFORE, Plaintiff demands judgment against Penn Medicine and Pennsylvania Hospital, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of Penn Medicine and Pennsylvania Hospital's conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from Penn Medicine's oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

DEMAND FOR JURY TRIAL

193. Plaintiff hereby demands a jury trial for all claims triable.

Dated: 7/16/2024

Respectfully submitted,

KLINE & SPECTER, P.C.

By: /s/ Tobias L. Millrood
Tobias L. Millrood, Esq.
Elizabeth A. Crawford, Esq.
Timothy A. Burke, Esq.
John P. O'Neill, Esq.

Benjamin Whiting, Esq. (pro hac vice)

KELLER POSTMAN LLC

150 N. Riverside Plaza, Suite 4100

Chicago, IL 60606

Telephone: (312) 741-5220

Fax: (312) 971-3502

ben.whiting@kellerpostman.com

EXHIBIT A-67

PHILADELPHIA COURT OF COMMON PLEAS PETITION/MOTION COVER SHEET

FOR COURT USE ONLY

ASSIGNED TO JUDGE:	ANSWER/RESPONSE DATE: 09/09/2024
--------------------	-------------------------------------

*Do not send Judge courtesy copy of Petition/Motion/Answer/Response.
Status may be obtained online at <http://courts.phila.gov>*

CONTROL NUMBER:

24084167

**(RESPONDING PARTIES MUST INCLUDE THIS
NUMBER ON ALL FILINGS)**

March 2022
Month Term, Year
No. 02617

Name of Filing Party:

ABBOTT LABORATORIES-DFT

STILLS ETAL VS MEAD JOHNSON NUTRITION
COMPANY ETAL

INDICATE NATURE OF DOCUMENT FILED:

☐ Petition (*Attach Rule to Show Cause*) ☒ Motion
☐ Answer to Petition ☐ Response to Motion

Has another petition/motion been decided in this case? ☒ Yes ☐ No

Is another petition/motion pending? ☒ Yes ☐ No

If the answer to either question is yes, you must identify the judge(s):

CARPENTER

TYPE OF PETITION/MOTION (see list on reverse side)

MOT-FOR ADMISSION PRO HAC VICE

PETITION/MOTION CODE
(see list on reverse side)
MTPHV

ANSWER / RESPONSE FILED TO (Please insert the title of the corresponding petition/motion to which you are responding):

I. CASE PROGRAM

DAY FORWARD/MAJOR JURY PROGRAM

Name of Judicial Team Leader: JUDGE LINDA
CARPENTER

Applicable Petition/Motion Deadline: N/AHas deadline been previously extended by the Court: N/A

II. PARTIES (required for proof of service)

(Name, address and **telephone number** of all counsel of record and unrepresented parties. Attach a stamped addressed envelope for each attorney of record and unrepresented party.)

JAMES A YOUNG

BURNS WHITE LLC 1835 MARKET STREET
SUITE 2700 , PHILADELPHIA PA 19103

SEAN P FAHEY

TROUTMAN PEPPER 3000 TWO LOGAN SQ
18TH AND ARCH STREETS , PHILADELPHIA
PA 19103-2799

JOSEPH E ONEIL

CAMPBELL CONROY & ONEIL 1205
WESTLAKES DR SUITE 330 , BERWYN PA
19312

MARQUES HILLMAN RICHESON

JONES DAY 901 LAKESINDE AVENUE NORTH
POINT , CLEVELAND OH 44114

THOMAS R KLINE

KLINE & SPECTER 1525 LOCUST ST., 19TH
FL. , PHILADELPHIA PA 19102

III. OTHER

By filing this document and signing below, the moving party certifies that this motion, petition, answer or response along with all documents filed, will be served upon all counsel and unrepresented parties as required by rules of Court (see PA. R.C.P. 206.6, Note to 208.2(a), and 440). Furthermore, moving party verifies that the answers made herein are true and correct and understands that sanctions may be imposed for inaccurate or incomplete answers.

August 19, 2024

SEAN P. FAHEY

(Attorney Signature/Unrepresented Party)

(Date)

(Print Name)

(Attorney I.D. No.)

The Petition, Motion and Answer or Response, if any, will be forwarded to the Court after the Answer/Response Date.

No extension of the Answer/Response Date will be granted even if the parties so stipulate.

KENNETH A MURPHY

TUCKER LAW GROUP, LLC 1801 MARKET
STREET SUITE 2500 , PHILADELPHIA PA
19103-6996

BENJAMIN WHITING

KELLER POSTMAN 150 N. RIVERSIDE PLAZA
SUITE 4100 , CHICAGO IL 60606

EVAN GLASSMAN

STEPTOE, LLP 1114 AVENUE OF THE
AMERICAS , NEW YORK NY 10036

T. ALLON RENFRO

SWANSON, MARTIN, & BELL, LLP 330 N.
WABASH, SUITE 3300 , CHICAGO IL 60611

FILED
Civil Administration
M. RIVERA

**IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
TRIAL DIVISION – CIVIL SECTION**

ALICE STILLS, <i>on her own behalf and as Parent</i>	:	
<i>and Natural Guardian of M.E., a Minor,</i>	:	PHILADELPHIA COUNTY
	:	COURT OF COMMON PLEAS
Plaintiffs,	:	TRIAL DIVISION
	:	
v.	:	
	:	
MEAD JOHNSON & COMPANY LLC; MEAD	:	MARCH TERM, 2022
JOHNSON NUTRITION COMPANY; ABBOTT	:	No. 220302617
LABORATORIES; THE PENNSYLVANIA	:	
HOSPITAL OF THE UNIVERSITY OF	:	
PENNSYLVANIA HEALTH SYSTEM, <i>d/b/a</i>	:	
PENNSYLVANIA HOSPITAL; and THE	:	
TRUSTEES OF THE UNIVERSITY OF	:	
PENNSYLVANIA, <i>d/b/a</i> PENN MEDICINE,	:	
	:	
Defendants.	:	

ORDER

AND NOW, this ____ day of _____, 2024, upon consideration of the Motion for Admission of Attorney Catherine T. Zeng *Pro Hac Vice*, it is hereby **ORDERED** and **DECREED** that the Motion for Admission *Pro Hac Vice* is hereby **GRANTED**, and Catherine T. Zeng, of Jones Day, is hereby admitted *Pro Hac Vice* for the purpose of representing Defendant Abbott Laboratories in the above-captioned action after obtaining the appropriate City of Philadelphia Business Privilege Tax License pursuant to 19-2602 of the Philadelphia Code. *Pro Hac Vice* Counsel shall pay all City Business and Wage Tax as required.

BY THE COURT:

J.

**IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
TRIAL DIVISION – CIVIL SECTION**

ALICE STILLIS, *on her own behalf and as Parent*
and Natural Guardian of M.E., a Minor,

Plaintiffs,

v.

MEAD JOHNSON & COMPANY LLC; MEAD
JOHNSON NUTRITION COMPANY; ABBOTT
LABORATORIES; THE PENNSYLVANIA
HOSPITAL OF THE UNIVERSITY OF
PENNSYLVANIA HEALTH SYSTEM, d/b/a
PENNSYLVANIA HOSPITAL; and THE
TRUSTEES OF THE UNIVERSITY OF
PENNSYLVANIA, d/b/a PENN MEDICINE,

Defendants.

:
:
: PHILADELPHIA COUNTY
: COURT OF COMMON PLEAS
: TRIAL DIVISION
:
:
:
: MARCH TERM, 2022
: No. 220302617
:
:
:

**DEFENDANT ABBOTT LABORATORIES' MOTION FOR THE
ADMISSION *PRO HAC VICE* OF CATHERINE T. ZENG, ESQUIRE**

AND NOW COMES the Defendant, Abbott Laboratories, by and through its undersigned counsel and sponsoring attorney, Sean P. Fahey, to file the instant Motion for Admission *Pro Hac Vice* of Catherine T. Zeng, and in support thereof, avers as follows:

1. Undersigned counsel, primary counsel, and attorney of record on the case moves this Honorable Court for the Admission *Pro Hac Vice* of Catherine T. Zeng, pursuant to Pa. R. Civ. P. 1012.1.

2. All information that is required under Section 81.504 of the IOLTA regulations has been provided to the IOLTA Board.

3. The fee required by Section 81.505(a) of the IOLTA regulations has been paid, and true and correct copies of the receipts are attached as Exhibit A.

4. Attorney Zeng, an attorney with Jones Day, is currently licensed to practice law in the State of California (admitted in 2007, bar number 251231). *See* Candidate Verification in Support of Motion for Admission of Attorney Catherine T. Zeng *Pro Hac Vice*, attached as Exhibit B.

5. Attorney Zeng has never been suspended, disbarred, or otherwise disciplined in any jurisdiction. *See* Exhibit B.

6. Attorney Zeng agrees to comply with and be bound by the applicable statutes, case law, and procedural rules of the Commonwealth of Pennsylvania, including the Pennsylvania Rules of Professional Conduct. *See* Exhibit B.

7. Attorney Zeng submits to the jurisdiction of the Pennsylvania Courts and the Pennsylvania Disciplinary Board with respect to acts and omissions occurring during the appearance in the above-captioned matters. *See* Exhibit B.

8. Attorney Zeng consents to the appointment of Sean P. Fahey as the agent upon whom service of process shall be made for all actions, including disciplinary actions. *See* Exhibit B.

9. The undersigned counsel submits that Attorney Zeng is a reputable and competent attorney, and highly recommends the candidate's admission. *See* Sponsor Verification in Support of Motion for Admission of Catherine T. Zeng *Pro Hac Vice*, attached as Exhibit C.

10. The undersigned counsel is acting as the sponsor of Attorney Zeng in the Courts of this Commonwealth for this case, and cases involving Defendant Abbott Laboratories' formula products currently pending in the Philadelphia Court of Common Pleas. *See* Exhibit B.

WHEREFORE, Defendant Abbott Laboratories and sponsoring attorney, Sean P. Fahey, respectfully request that this Honorable Court grant Defendant's Motion for Admission *Pro Hac Vice* of Attorney Zeng.

Dated: August 19, 2024

Respectfully submitted,

/s/ Sean P. Fahey

Sean P. Fahey (PA 73305)

TROUTMAN PEPPER

HAMILTON SANDERS LLP

3000 Two Logan Square

Eighteenth and Arch Streets

Philadelphia, PA 19103

Telephone: (215) 981-4296

Sean.Fahey@Troutman.com

Attorney for Defendant

Abbott Laboratories

EXHIBIT A



SUPREME COURT OF PENNSYLVANIA
PENNSYLVANIA INTEREST ON
LAWYERS TRUST ACCOUNT BOARD

August 16, 2024

CATHERINE TARA ZENG, Esq.
JONES DAY
1755 EMBARCADERO ROAD
PALO ALTO, CA 94303

SENT TO CATHERINE ZENG VIA Email: CZENG@JONESDAY.COM

Dear Attorney ZENG:

This letter serves as the fee payment certification referenced in 204 Pa Code §81.503 and acknowledges receipt of the \$375.00 fee paid by Online Payment on this date related to your pursuit for admission *pro hac vice* in the case identified as STILLS ET AL VS MEAD JOHNSON & COMPANY LLC, ET AL, no. 220302617, filed in Court of Common Pleas of Philadelphia County.

You should refer to Pa Rule of Civil Procedure 1012.1, local court rules, and other regulations of 204 Pa Code §81.501 et. seq. concerning additional requirements related to seeking *pro hac vice* admission.

Sincerely,

A handwritten signature in blue ink that reads "Stephanie S. Libhart".

Stephanie S. Libhart
Executive Director

cc: SEAN P. FAHEY, Esq.

Sean.fahey@troutman.com

Pennsylvania Judicial Center
601 Commonwealth Ave., Ste. 2400
PO Box 62445, Harrisburg, PA 17106-2445
717/238-2001 · 888/PA-IOLTA (724-6582) · 717/238-2003 FAX
paiolta@pacourts.us · www.paiolta.org

EXHIBIT B

**IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
TRIAL DIVISION – CIVIL SECTION**

ALICE STILLS, *on her own behalf and as Parent*
and Natural Guardian of M.E., a Minor,

Plaintiffs,

v.

MEAD JOHNSON & COMPANY LLC; MEAD
JOHNSON NUTRITION COMPANY; ABBOTT
LABORATORIES; THE PENNSYLVANIA
HOSPITAL OF THE UNIVERSITY OF
PENNSYLVANIA HEALTH SYSTEM, *d/b/a*
PENNSYLVANIA HOSPITAL; and THE
TRUSTEES OF THE UNIVERSITY OF
PENNSYLVANIA, *d/b/a* PENN MEDICINE,

Defendants.

PHILADELPHIA COUNTY
COURT OF COMMON PLEAS
TRIAL DIVISION

MARCH TERM, 2022
No. 220302617

**CANDIDATE VERIFICATION IN SUPPORT OF MOTION FOR
ADMISSION OF ATTORNEY CATHERINE T. ZENG *PRO HAC VICE***

I, Catherine T. Zeng, do hereby verify that the following statements are true and correct:

1. I am currently licensed to practice law in the State of California (admitted in 2007, bar number 251231).

2. I am a member in good standing and eligible to practice before the State Bar of California. I am not currently suspended or disbarred by that Bar.

3. I am admitted to practice before the U.S. Courts of Appeals for the Ninth Circuit (admitted 2009), the U.S. Court of Appeals for the Federal Circuit (admitted 2022), the U.S. District Court for the Northern District of California (admitted 2008), the U.S. District Court for the Central District of California (admitted 2007), the U.S. District Court for the Eastern

District of California (admitted 2008), and the U.S. District Court for the Southern District of California (admitted 2008).¹

4. I have never been suspended, disbarred, or otherwise disciplined in any jurisdiction nor am I subject to any disciplinary proceedings.

5. I also am involved in the following pending action in the Philadelphia Court of Common Pleas in which I am applying for admission *pro hac vice*: *Abdullah, et al. v. Mead Johnson & Company, LLC, et al.* (Case No. 220302583).

6. I agree to comply with and be bound by the applicable statutes, case law, and procedural rules of the Commonwealth of Pennsylvania, including the Pennsylvania Rules of Professional Conduct.

7. I agree to submit to the jurisdiction of the Pennsylvania Courts and the Pennsylvania Disciplinary Board with respect to the acts and omissions occurring during appearance in the above-captioned matter.

8. I consent to the appointment of my sponsoring attorney, Sean P. Fahey, as the agent upon whom service of process shall be made for all actions, including disciplinary actions that may arise during the above-captioned matter.

9. I verify that the above statements are true and correct.

Dated: August 19, 2024

Respectfully submitted,

/s/ Catherine T. Zeng
Catherine T. Zeng
JONES DAY
1755 Embarcadero Road
Palo Alto, CA 94303
650.687.4132
czeng@jonesday.com

¹ Attorney Zeng practiced under her maiden name, Catherine Tara Broderick, in all jurisdictions in which she was admitted prior to 2011.

EXHIBIT C

**IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
TRIAL DIVISION – CIVIL SECTION**

ALICE STILLIS, <i>on her own behalf and as Parent</i>	:	
<i>and Natural Guardian of M.E., a Minor,</i>	:	PHILADELPHIA COUNTY
	:	COURT OF COMMON PLEAS
Plaintiffs,	:	TRIAL DIVISION
	:	
v.	:	
	:	
MEAD JOHNSON & COMPANY LLC; MEAD	:	MARCH TERM, 2022
JOHNSON NUTRITION COMPANY; ABBOTT	:	No. 220302617
LABORATORIES; THE PENNSYLVANIA	:	
HOSPITAL OF THE UNIVERSITY OF	:	
PENNSYLVANIA HEALTH SYSTEM, <i>d/b/a</i>	:	
PENNSYLVANIA HOSPITAL; and THE	:	
TRUSTEES OF THE UNIVERSITY OF	:	
PENNSYLVANIA, <i>d/b/a</i> PENN MEDICINE,	:	
Defendants.		

**SPONSOR VERIFICATION IN SUPPORT OF MOTION FOR ADMISSION
OF CATHERINE T. ZENG *PRO HAC VICE***

I, Sean P. Fahey, do hereby verify that the following statements are true and correct:

1. I am currently licensed to practice law in Pennsylvania (Bar No. 73305), and I am the attorney of record in the above-captioned action.
2. After reasonable investigation, I reasonably believe Attorney Catherine T. Zeng to be a reputable and competent attorney, and I am in a position to recommend Attorney Zeng's admission.
3. I verify that the above statements are true and correct.

Dated: August 19, 2024

Respectfully submitted,

/s/ Sean P. Fahey

Sean P. Fahey (PA 73305)

TROUTMAN PEPPER

HAMILTON SANDERS LLP

3000 Two Logan Square

Eighteenth and Arch Streets

Philadelphia, PA 19103

Telephone: (215) 981-4296

Sean.Fahey@Troutman.com

CERTIFICATE OF COMPLIANCE

I, Sean P. Fahey, hereby certify that this filing complies with the provisions of the Public Access Policy of the Unified Judicial System of Pennsylvania: Case Records of the Appellate and Trial Courts that require filing confidential information and documents differently than non-confidential information and documents.

Dated: August 19, 2024

/s/ Sean P. Fahey
Sean P. Fahey (PA 73305)
TROUTMAN PEPPER
HAMILTON SANDERS LLP

CERTIFICATE OF SERVICE

I, Sean P. Fahey, hereby certify that this 19th day of August 2024, I served a true and correct copy of the foregoing MOTION FOR ADMISSION OF ATTORNEY CATHERINE T. ZENG *PRO HAC VICE* via the Court's Electronic Filing System and by email on all counsel of record.

/s/ Sean P. Fahey

Sean P. Fahey (PA 73305)

TROUTMAN PEPPER

HAMILTON SANDERS LLP

EXHIBIT A-68

FILED
03 SEP 2024 04:13 pm
Civil Administration
J. BOYD

IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
TRIAL DIVISION - CIVIL

CHRISTINA TAYLOR, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	MARCH TERM, 2022 No. 220302606
TERRAINE ABDULLAH, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	MARCH TERM, 2022 No. 02583
HOLLI CARTER, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	MARCH TERM, 2022 No. 220302588
SHONDERA DRAYTON, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	MARCH TERM, 2022 No. 02594
CATHERINE McMILLIAN, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	APRIL TERM, 2022 No. 220400140
LOREN SANDERS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	APRIL TERM, 2022 No. 220400153
SAMAYA SHORT, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	APRIL TERM, 2022 No. 220400159

ALICE STILLIS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : : :	MARCH TERM, 2022 No. 220302617
GINA WIEGER, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : : :	MARCH TERM, 2022 No. 220302601
STEPHANIE WILKERSON, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : : :	SEPTEMBER TERM, 2023 No. 230900730
MELVENIA WILLIAMS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : : :	APRIL TERM, 2022 No. 220400141

ORDER

AND NOW this the _____ day of _____, 2024, upon consideration of Defendants The Pennsylvania Hospital of the University of Pennsylvania Health System and the Trustees of the University of Pennsylvania's Preliminary Objections to the Plaintiffs' Complaint, Plaintiffs' Answer thereto, and all other appropriate considerations, it is hereby ORDERED, ADJUDGED and DECREED that Defendants' Preliminary Objections are OVERRULED.

BY THE COURT

J.

KLINE & SPECTER, P.C.

THOMAS R. KLINE, ESQUIRE

Attorney I.D. No. 28895

TOBIAS MILLROOD, ESQUIRE

Attorney I.D. No. 77764

ELIZABETH CRAWFORD, ESQUIRE

Attorney I.D. No. 313702

MELISSA MERK, ESQUIRE

Attorney I.D. No. 90363

TIMOTHY A. BURKE, ESQUIRE

Attorney I.D. 320927

1525 Locust Street, 19th Floor

Philadelphia, PA 19102

(215) 772-1000/(215) 772-1359 fax.

Attorney for Plaintiffs

IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
TRIAL DIVISION - CIVIL

CHRISTINA TAYLOR, et al., Plaintiff,	:	
v.	:	MARCH TERM, 2022
MEAD JOHNSON & COMPANY, LLC, et al.,	:	No. 220302606
Defendants.	:	
TERRAINE ABDULLAH, et al., Plaintiff,	:	
v.	:	MARCH TERM, 2022
MEAD JOHNSON & COMPANY, LLC, et al.,	:	No. 02583
Defendants.	:	
HOLLI CARTER, et al., Plaintiff,	:	
v.	:	MARCH TERM, 2022
MEAD JOHNSON & COMPANY, LLC, et al.,	:	No. 220302588
Defendants.	:	
SHONDERA DRAYTON, et al., Plaintiff,	:	
v.	:	MARCH TERM, 2022
MEAD JOHNSON & COMPANY, LLC, et al.,	:	No. 02594
Defendants.	:	

CATHERINE McMILLIAN, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	APRIL TERM, 2022 No. 220400140
LOREN SANDERS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	APRIL TERM, 2022 No. 220400153
SAMAYA SHORT, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	APRIL TERM, 2022 No. 220400159
ALICE STILLIS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	MARCH TERM, 2022 No. 220302617
GINA WIEGER, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	MARCH TERM, 2022 No. 220302601
STEPHANIE WILKERSON, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	SEPTEMBER TERM, 2023 No. 230900730
MELVENIA WILLIAMS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	APRIL TERM, 2022 No. 220400141

**PLAINTIFFS' REPSONSE TO PRELMINIARY OBJECTIONS OF DEFENDANTS THE
PENNSYLVANIA HOSPITAL OF THE UNVIERSTY OF PENNSYLVANIA HEALTH
SYSTEM AND THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA TO
PLAINTIFFS' SECOND AMENDED COMPLAINTS**

Plaintiffs, by and through their counsel, Kline & Specter, P.C., hereby oppose Defendants' Preliminary Objections and responds to Defendants' Preliminary Objections and Evidentiary Exhibits as follows:¹

1. Admitted.
2. Admitted.
3. Admitted.
4. Admitted.
5. Admitted.
6. Denied as a conclusion of law to which no response is required. By way of further response, please see Plaintiffs' attached Memorandum of Law.
7. Denied as a conclusion of law to which no response is required. By way of further response, please see Plaintiffs' attached Memorandum of Law.
8. Admitted.
9. Admitted.
10. Admitted.
11. Admitted.

¹ To conserve judicial resources, and pursuant to the practice recommended by the Court at the July 24, 2023 conference, Plaintiffs file this opposition on the instant docket and incorporate by reference the arguments herein in each of the following actions in which plaintiffs filed second amended complaints: *Abdullah v. Mead Johnson & Company, LLC, et al.*, No. 220302583; *Carter v. Mead Johnson & Company, LLC, et al.*, No. 220302588; *Drayton v. Mead Johnson & Company, LLC, et al.*, No. 220302594; *Gray v. Mead Johnson & Company, LLC, et al.*, No. 220400216; *Hollingsworth v. Mead Johnson & Company, LLC, et al.*, No. 230900791; *Kajuffa v. Mead Johnson & Company, LLC, et al.*, No. 220302978; *Mays v. Mead Johnson & Company, LLC, et al.*, No. 220302963; *McMillian v. Mead Johnson & Company, LLC, et al.*, No. 220400140; *Parker v. Mead Johnson & Company, LLC, et al.*, No. 220302983; *Ross v. Mead Johnson & Company, LLC, et al.*, No. 220302981; *Sanders v. Mead Johnson & Company, LLC, et al.*, No. 220400153; *Short v. Mead Johnson & Company, LLC, et al.*, No. 220400159; *Stills v. Mead Johnson & Company, LLC, et al.*, No. 220302617; *Taylor v. Mead Johnson & Company, LLC, et al.*, No. 220302606; *Thomas v. Mead Johnson & Company, LLC, et al.*, No. 220400158; *Tucker v. Mead Johnson & Company, LLC, et al.*, No. 230900867; *Wieger v. Mead Johnson & Company, LLC, et al.*, No. 220302601; *Wilkerson v. Mead Johnson & Company, LLC, et al.*, No. 230900730; and *Williams v. Mead Johnson & Company, LLC, et al.*, No. 220400141.

12. Denied as a conclusion of law to which no response is required. By way of further response, please see Plaintiffs' attached Memorandum of Law.

13. Denied as a conclusion of law to which no response is required. By way of further response, please see Plaintiffs' attached Memorandum of Law.

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WHEREFORE, for the reasons more fully set forth in Plaintiff's accompanying Memorandum of Law, Plaintiff respectfully requests that this Honorable Court deny Defendants' Preliminary Objections, or, in the alternative, Order that Plaintiff is permitted leave to amend their Complaint.

Respectfully submitted,

KLINE & SPECTER,
A Professional Corporation

Date: September 3, 2024

By: /s/Timothy A. Burke, Esquire

THOMAS KLINE, ESQUIRE
TOBI MILLROOD, ESQUIRE
ELIZABETH CRAWFORD, ESQUIRE
TIMOTHY BURKE, ESQUIRE
Attorneys for Plaintiffs

KELLER POSTMAN
BEN WHITING, ESQUIRE (*Pro Hac Vice*)
AMELIA FRENKEL, ESQUIRE
Attorneys for Plaintiffs

KLINE & SPECTER, P.C.

THOMAS R. KLINE, ESQUIRE

Attorney I.D. No. 28895

TOBIAS MILLROOD, ESQUIRE

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(215) 772-1000/(215) 772-1359 fax.

Attorney for Plaintiffs

IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
TRIAL DIVISION - CIVIL

CHRISTINA TAYLOR, et al., Plaintiff,	:	
v.	:	MARCH TERM, 2022
MEAD JOHNSON & COMPANY, LLC, et al.,	:	No. 220302606
Defendants.	:	
TERRAINE ABDULLAH, et al., Plaintiff,	:	
v.	:	MARCH TERM, 2022
MEAD JOHNSON & COMPANY, LLC, et al.,	:	No. 02583
Defendants.	:	
HOLLI CARTER, et al., Plaintiff,	:	
v.	:	MARCH TERM, 2022
MEAD JOHNSON & COMPANY, LLC, et al.,	:	No. 220302588
Defendants.	:	
SHONDERA DRAYTON, et al., Plaintiff,	:	
v.	:	MARCH TERM, 2022
MEAD JOHNSON & COMPANY, LLC, et al.,	:	No. 02594
Defendants.	:	

CATHERINE McMILLIAN, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	APRIL TERM, 2022 No. 220400140
LOREN SANDERS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	APRIL TERM, 2022 No. 220400153
SAMAYA SHORT, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	APRIL TERM, 2022 No. 220400159
ALICE STILLIS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	MARCH TERM, 2022 No. 220302617
GINA WIEGER, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	MARCH TERM, 2022 No. 220302601
STEPHANIE WILKERSON, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	SEPTEMBER TERM, 2023 No. 230900730
MELVENIA WILLIAMS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	APRIL TERM, 2022 No. 220400141

**PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF THEIR REPSONSE TO
PRELMINIARY OBJECTIONS OF DEFENDANTS THE PENNSYLVANIA HOSPITAL
OF THE UNVIERSITY OF PENNSYLVANIA HEALTH SYSTEM AND THE
TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA TO PLAINTIFFS' SECOND
AMENDED COMPLAINTS**

I. Matter Before the Court

Plaintiffs, by and through their counsel, Kline & Specter, P.C., hereby oppose Defendants' Preliminary Objections and respond to the Defendants' Preliminary Objections and Evidentiary Exhibits as follows:²

II. Counter Statement of Questions Involved

1. Whether this Honorable Court should deny Defendants' Preliminary Objections as to Plaintiffs' "Failure to Warn" claims where Plaintiffs have adequately alleged that bovine-based formula is unreasonably dangerous and substantially increases the risk for the development of NEC in preterm infants, and where Plaintiffs are not required under the pleading standard to cite to evidence (such as medical studies) in their Complaint in support of ultimate issues that will have to be proven at trial?

Suggested answer in the affirmative.

2. Whether this Honorable Court should deny Defendants' Preliminary Objections as to Plaintiffs' "Failure to Warn" claims where Plaintiffs have adequately alleged Defendants breached their duty as the hospital system and/or healthcare provider by failing to adequately communicate the facts, risks, benefits, and alternatives associated

² To conserve judicial resources, and pursuant to the practice recommended by the Court at the July 24, 2023 conference, Plaintiffs file this opposition on the instant docket and incorporate by reference the arguments herein in each of the following actions in which plaintiffs filed second amended complaints: *Abdullah v. Mead Johnson & Company, LLC, et al.*, No. 220302583; *Carter v. Mead Johnson & Company, LLC, et al.*, No. 220302588; *Drayton v. Mead Johnson & Company, LLC, et al.*, No. 220302594; *Gray v. Mead Johnson & Company, LLC, et al.*, No. 220400216; *Hollingsworth v. Mead Johnson & Company, LLC, et al.*, No. 230900791; *Kajuffa v. Mead Johnson & Company, LLC, et al.*, No. 220302978; *Mays v. Mead Johnson & Company, LLC, et al.*, No. 220302963; *McMillian v. Mead Johnson & Company, LLC, et al.*, No. 220400140; *Parker v. Mead Johnson & Company, LLC, et al.*, No. 220302983; *Ross v. Mead Johnson & Company, LLC, et al.*, No. 220302981; *Sanders v. Mead Johnson & Company, LLC, et al.*, No. 220400153; *Short v. Mead Johnson & Company, LLC, et al.*, No. 220400159; *Stills v. Mead Johnson & Company, LLC, et al.*, No. 220302617; *Taylor v. Mead Johnson & Company, LLC, et al.*, No. 220302606; *Thomas v. Mead Johnson & Company, LLC, et al.*, No. 220400158; *Tucker v. Mead Johnson & Company, LLC, et al.*, No. 230900867; *Wieger v. Mead Johnson & Company, LLC, et al.*, No. 220302601; *Wilkerson v. Mead Johnson & Company, LLC, et al.*, No. 230900730; and *Williams v. Mead Johnson & Company, LLC, et al.*, No. 220400141.

with the use of bovine-based formula to preterm infants' parents, so that the parents could knowingly choose whether to consent on behalf of preterm infants?

Suggested answer in the affirmative.

3. Whether this Honorable Court should deny Defendants' Preliminary Objections as to Plaintiffs' "Corporate Negligence" cause of action where Defendant hospital systems engaged in systemic negligence by failing to enact policies and procedures to prevent bovine-milk based formula from being fed to pre-term infants.

Suggested answer in the affirmative.

4. Whether this Honorable Court should deny Defendants' Preliminary Objections as to Plaintiffs' "Corporate Negligence" cause of action where Defendant Trustees of the University of Pennsylvania are a governing body and overseer of the Hospital of the University of Pennsylvania ("HUP"), who are in charge of enacting the HUP policies and procedures at issue in Plaintiffs' Complaint, subjecting them to Plaintiffs' Corporate Negligence claims.

Suggested answer in the affirmative.

5. Whether this Honorable Court should deny Defendants Preliminary Objections as to sufficiency of the pleadings where Plaintiffs have sufficient and adequately summarized material facts that inform and notify the Defendants of the claims which they must defend?

Suggested answer in the affirmative.

6. Whether this Honorable Court should deny Defendants Preliminary Objections as to punitive damages where Plaintiffs have adequately plead facts providing a basis for punitive damages?

Suggested answer in the affirmative.

7. Whether this Honorable Court should deny Defendants Preliminary Objections for Plaintiff Parents claims where the Plaintiff parents have sufficient plead counts for individual harm as well as the harm on behalf of the Minor Plaintiff in the Complaint and where those claims are not barred by the statute of limitations?

Suggested answer in the affirmative.

8. Whether this Honorable Court should deny Defendants Preliminary Objections where Plaintiff's necessary verification has been filed by way of a praecipe to attach to Plaintiffs' Complaint?

Suggested answer in the affirmative.

III. Plaintiffs Have Sufficiently Alleged that Pennsylvania Hospital and HUP Failed to Warn Healthcare Professionals and Parents of the Unreasonable Risk of NEC Posed by Bovine-Based Formula to Premature Infants under Count VI.

The moving Hospital Defendants failed to warn parents of premature infants, and their guardian parents, of the risk associated with goods they were supplying to those infants while under their care. A supplier of goods will be liable for their negligent failure to warn foreseeable users of that chattel under Section 388 of the Second Restatement of Torts, which has been incorporated into Pennsylvania law, if:

One who supplies directly or through a third person a chattel for another to use is subject to liability to those whom the supplier should expect to use the chattel with the consent of the other or to be endangered by its probable use, for the physical harm caused by the use of the chattel in the manner for which and by a person for whose use it is supplied, if the supplier

- (a) knows or has reason to know that the chattel is or is likely to be dangerous for the use for which it is supplied; and
- (b) has no reason to believe that those for whose use the chattel is supplied will realize its dangerous condition; and
- (c) fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be dangerous.

RST 2 § 388.

See, e.g., Binder v. Jones & Laughlin Steel Corp., 360 Pa. Super. 390, 396 (1987) (applying RST 2 § 388 to a metal part supplier). Section 388 applies to any supplier of a chattel to another, as explained in Section 388's accompanying comment:

c. Persons included as "suppliers." The rules stated in this Section and throughout this Topic apply to determine the liability of any person who for any purpose or in any manner gives possession of a chattel for another's use, or who permits another to use or occupy it while it is in his own possession or control, without disclosing his knowledge that the chattel is dangerous for the use for which it is supplied or for which it is permitted to be used. These rules, therefore, apply to sellers, lessors, donors, or lenders, irrespective of whether the chattel is made by them or by a third person. They apply to all kinds of bailors, irrespective of whether the bailment is for a reward or gratuitous, and irrespective of whether the bailment is for use, transportation, safekeeping, or repair. They also apply to one who undertakes the repair of a chattel and who delivers it back with knowledge that it is defective because of the work which he is employed to do upon it.

See § 403 RST 2 § 388 cmt. C; *see also Maize v. Atlantic Refin. Co.*, 352 Pa. 51, 56 (1945) ("This court has laid down the rule that anyone who is responsible for the existence of any dangerous instrumentality or substance with which persons are likely to come in contact must 'impose a measure of control that is adequate to the protection of human beings' from it.").

A supplier under this Section will be liable if they supply a chattel for use, which they know or should have known is dangerous, and they fail to warn the user of that danger and to advise proper precautions. *See Hopkins v. E.I. Du Pont De Nemours & Co.*, 199 F.2d 930, 932-33 (3d Cir. 1952) (applying Pennsylvania law) (citing *Maize*, 352 Pa. at 55). Under this Section, a supplier's disclosures will be insufficient if they fall below the standard of care that would be taken by a "reasonable man in a similar situation." *Binder*, 360 Pa. Super. at 398. The greater the potential danger of the instrumentality, the greater the duty to warn against foreseeable and known dangers. *See Thomas v. Arvon Prod's*, 424 Pa. 365, 369-70 (1967); 352 Pa. at 56. "[T]he care to be exercised in a particular case must always be proportionate to the seriousness of the

consequences which are *reasonably* to be anticipated as a result of the conduct in question.” 360 Pa. Super. at 398 (citations omitted) (emphasis in original). When another actor “acts as the nexus between the supplier and the actual user of the dangerous chattel,” the supplier cannot “escape the duty to disclose by cavalierly relying on the [other actor] to somehow pass the information along to the actual user.” *Id.*

In this case, Defendants failed to adequately communicate the facts, risks, benefits, and alternatives associated with the use of bovine-based formula to preterm infants’ parents, so that could knowingly choose whether to consent on behalf of preterm infants. Defendants’ duty to warn was even greater by virtue of the fact that parents could not be expected to know the risk of NEC associated with bovine-based formula and given the seriousness of NEC as a disease.

Defendants Pennsylvania Hospital and Hospital of the University of Pennsylvania argue that Plaintiff cannot state a claim for failure to warn because they were not a manufacturer of formula. However, since Plaintiffs’ claims sounds in negligence, Defendant does not need to be a commercial manufacturer. Here, Defendants were responsible for providing the infant formula to medical practitioners and the NICU at their hospitals and by extension, to patients, and were therefore, suppliers for purposes of Section 388. Moreover, Plaintiff has alleged that the formula caused an increased risk when fed to infants, in other words, when it was used for its intended usage. Plaintiffs’ Complaint alleges that hospitals, including HUP, entered into financially advantageous relationships with codefendant manufacturers Abbott and Mead at various times to purchase, supply, and distribute bovine-based formula to their medical professionals, knowing that these products would then be provided to infants being treated by these providers in their facilities. Hence, Defendants knowingly supplied these instrumentalities to end users, who were not merely foreseeable, but the intended recipients of the formula. Further, the Hospitals’ liability is not

negated by the fact that others acted as intermediaries when they negligently failed to warn their own providers of these risks and facilitated their providers receiving inaccurate information, which inaccurately downplayed the risk of NEC, from the manufacturers' sales personnel. Moreover, as shown by their own internal correspondence and the relevant academic and medical literature surrounding NEC and bovine-formula in pre-term infants, Defendants knew or should have known that bovine-based formula posed an increased risk of NEC to premature infants. Since NEC is a dangerous and potentially fatal disease, there was an even greater duty on Defendants to adequately warn foreseeable users of this known risk or take steps to make sure that the intermediaries they controlled, namely medical professionals, reliably communicated these risks to parents. Hence, the Hospitals failed to warn parents of the dangerous conditions associated with the formula, which parents had no reason to suspect, while supplying this formula for purposes of Section 388.

IV. Plaintiffs' Complaint Sufficiently Alleges Facts That Support Their Claims of Corporate Liability of The Moving Health Care Provers, Thus These Claims Should not Be Dismissed

In *Thompson v. Nason Hospital*, 591 A.2d 703, 708 (Pa. 1991), the Pennsylvania Supreme Court recognized the doctrine of corporate liability, holding that a hospital may be found directly liable for negligence if it fails to meet any of the following four duties: (1) a duty to use reasonable care in the maintenance of safe and adequate facilities and equipment; (2) a duty to select and retain only competent physicians; (3) a duty to oversee all persons who practice medicine within its walls as to patient care; and (4) a duty to formulate, adopt and enforce adequate rules and policies to ensure quality care for patients.

In considering whether the plaintiff could sustain corporate negligence claims based on these allegations, the *Edwards* court analyzed the *Thompson* decision and delineated the standards required to sustain such a claim:

The Thompson theory of corporate liability will not be triggered every time something goes wrong in a hospital which harms a patient . . . To establish corporate negligence, a plaintiff must show more than an act of negligence by an individual for whom the hospital is responsible. Rather, *Thompson* requires a plaintiff to show that **the hospital itself is breaching a duty and is somehow substandard**...Thompson contemplates a **kind of ‘systemic negligence’**...

Id. at 1386-87 (citations omitted and emphasis added).

The facts and allegations in Plaintiffs’ complaint clearly and succinctly articulate claims of a “systemic negligence” taking place at Penn and HUP, namely that the hospital engaged in a practice of entering into financially advantageous relationships with codefendant manufacturers Abbott and Mead at various times to purchase, supply, and distribute bovine-based formula to their medical professionals, knowing that these products would then be provided to infants being treated by these providers in their facilities. Hence, Defendants knowingly supplied these instrumentalities to end users, who were not merely foreseeable, but the intended recipients of the formula. Further, the Hospitals’ liability is not negated by the fact that others acted as intermediaries when they negligently failed to warn their own providers of these risks and facilitated their providers receiving inaccurate information, which inaccurately downplayed the risk of NEC, from the manufacturers’ sales personnel, because it is alleged that the hospitals themselves decided which formula product would be stocked and supplied in their respective NICU’s and pre-term infant hospital facilities.

Further, Plaintiffs allege in their Complaint that:

A reasonable hospital under the same or similar circumstances would have overseen and managed its healthcare professionals and medical staff to ensure that they received proper training and updating on the risks associated with feeding cow’s milk-based formula to premature infants. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its duty to oversee its healthcare professionals and medical staff who provide patient care, the Injured Infant would not have been exposed to the Defendant Manufacturers’ cow’s milk-based products. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital’s failure to oversee its healthcare professionals and medical staff on the

danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

See Plaintiffs' Complaint, at ¶¶190-192.

Moreover, as shown by their own internal correspondence and the relevant academic and medical literature surrounding NEC and bovine-formula in pre-term infants, Defendants knew or should have known that bovine-based formula posed an increased risk of NEC to premature infants. See Ex. A, *Taylor v. Abbott Laboratories, et al.* Second Amended Complaint, at ¶¶168-193.

Finally, corporate liability can attach to a hospital system when there is a duty to formulate, adopt and enforce adequate rules and policies to ensure quality care for patients. Here Moving Defendants are the responsible corporate entities of Pennsylvania Hospital and Hospital of the University of Pennsylvania (HUP). Defendants had the duty to formulate, adopt, and enforce adequate rules and policies regarding the administration of certain formulations of baby formulas to pre-term infants in their care, and to not supply and/or have a policy of not administering bovine based formula to preterm infants which is shown in the literature to increase risk of developing NEC to those patients. *Id.* Therefore, Plaintiffs' Corporate Liability claims should not be dismissed.

V. Plaintiffs' Complaint Sufficiently Alleges that Defendant Colluded to Distribute and Sell Dangerous Products, and Failed to Warn Medical Practitioners of these Risks. Plaintiffs' Claims for Punitive Damages Should Therefore Not be Dismissed.

Punitive damages may be awarded for "conduct that is outrageous, because of the defendant's evil motive or his reckless indifference to the rights of others." *Hutchison v. Luddy*, 582 Pa. 114, 121 (2005) (quoting *Feld v. Merriam*, 506 Pa. 383, 395 (1984)). Punitive damages must be based on conduct that is "wanton," "willful," or "reckless." 582 Pa. at 121. As such, in

Pennsylvania, to withstand preliminary objections, a plaintiff must allege that (1) a defendant had a subjective appreciation of the risk of harm to which the plaintiff was exposed and that (2) he acted, or failed to act, as the case may be, in conscious disregard of that risk. *Id.* Pennsylvania courts have repeatedly held that a jury should determine whether punitive damages are warranted. *SHV Coal, Inc. v. Cont'l Grain Co.*, 526 Pa. 489, 495 (1991) (“The determination of whether a person’s actions arise to outrageous conduct lies within the sound discretion of the fact-finder and will not be disturbed by an appellate court so long as that discretion has not been abused.”). Furthermore, to the extent that there is any doubt about whether the standard for punitive damages has been met, that doubt must be resolved in the Plaintiff’s favor at this stage. *See Theodore v. Del. Valley Sch. Dist.*, 575 Pa. 321, 333 (2003).

For example, in *Hall v. Episcopal Long Term Care*, plaintiffs alleged that the neglect of a nursing home’s staff led to the plaintiff-decedent’s death. 54 A.3d 381, 394-95 (Pa. Super. 2012). The plaintiff argued that the “evidence of understaffing, falsification of records, substandard facility conditions, and improper treatment of the deceased’s pain, all of which Episcopal failed to correct despite knowledge of such” demonstrated sufficiently knowing conduct to underly punitive damages. *Id.* at 394-95. The trial court concluded that punitive damages were not warranted because the nursing home’s negligence “did not rise to the level of reckless disregard.” *Id.* at 397 (quoting the trial court opinion). The Superior court reversed the trial court’s directed verdict on the issue of punitive damages and held that the issue of punitive damages should have proceeded to the jury as “the Estate presented evidence establishing Episcopal acted in an outrageous fashion in reckless disregard to the rights of others and created an unreasonable risk of physical harm to the residents of the nursing home.” *Id.* at 396-97. In so holding, the Court discussed *Scampone*, where the Superior Court likewise held that the issue of punitive damages

against one defendant should have proceeded to a jury, since they jointly engaged in conduct with a codefendant that warranted punitive damages against that defendant. *Scampone v. Grane Healthcare Co.*, 169 A.3d 600, 627 (Pa. Super. 2017) (“the punitive damages trial must include Highland since, according to Mr. Scampone’s evidence, its employees colluded with Grane employees in some of the actions that warranted imposition of punitive damages, i.e., the alteration of patient records.”).

In this case, Plaintiff has alleged that Penn Medicine and HUP purchased, supplied, and distributed bovine-based products, manufactured by codefendants Abbott and Mead, which they knew posed an increased risk of a serious and deadly disease to infants, in order to cut costs. The Hospital Defendants colluded with codefendants to supply Abbott and Mead’s products to medical professionals at HUP and failed to warn these professionals about the known risks of these products. Defendants failed to warn healthcare professionals of the known risks of NEC posed by these products, and failed to establish a practice or policy of ensuring that these products were not fed to premature infants, as established in scientific literature, and instead arranged for these treaters to interact with Abbott and Mead salespersons. They then failed to prevent codefendants’ sales representatives from making misrepresentations about the increased risk of NEC posed by bovine, instead of human-nutrition based products, and failed to correct these misrepresentations. As a result, Defendants knowingly distributed codefendants’ products to practitioners who they knew would provide them to patients, in order to save costs to the Hospitals. Hence, Defendants colluded to pose an unreasonable risk of harm to minor Plaintiff and other infants.

VI. Plaintiff Has Adequately Pled the Facts and Damages at Issue

Defendant asserts that Plaintiffs’ Complaint fails to adequately plead facts regarding liability and injuries claimed. Defendant is wrong and their Preliminary Objections should be

overruled. A complaint must give a defendant fair notice of the plaintiff's claims and a summary of the material facts that support those claims. Pa. R.C.P. 1019(a). As the Superior Court has noted:

Rule 1019(a) requires fact pleading. The purpose of 1019(a) is to require the pleader to disclose the material facts **sufficient to enable the adverse party to prepare his case**. A complaint therefore must do more than give the defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests. It should formulate the issues by fully summarizing the material facts. Material facts are ultimate facts, i.e., those facts essential to support the claim. **Evidence from which such facts may be inferred not only need not but should not be alleged.** Allegations will withstand challenge under 1019(a) if (1) they contain averments of all of the facts a plaintiff will eventually have to prove in order to recover, and (2) they are sufficiently specific so as to enable defendant to prepare his defense.

Baker v. Rangos, 324 A.2d 498, 505-506 (Pa. Super. 1974) (citations and internal quotations omitted)(emphasis added).

In assessing whether particular paragraphs in a complaint satisfy this requirement, they must be read in context with all other allegations in the complaint to determine whether the defendant has been provided adequate notice of the claim against which it must defend. *Yacoub v. Lehigh Valley Med. Associates, P.C.*, 805 A.2d 579, 589 (Pa. Super. Ct. 2002). When determining whether certain allegations are sufficiently specific, Pennsylvania Law requires that the allegation be read in the context of the entire Complaint and not in a vacuum. *Hook v. L.B. Smith, Inc.*, 69 D&C 2d 420 (1974); *Duchess Underwear Co. V. Sivan Manuf. Co.*, 75 D&C 185 (1950); accord *Cmwlth v. Bell Tel Co.*, 121 Pa. Cmwlth 642, 649, 551 A2d 602 (1988). The Court must determine “whether the complaint is sufficiently clear to enable the Defendant to prepare his defense or [if it] informs the Defendant with accuracy and completeness of the specific basis on which recovery is sought so that he may know without question upon what grounds to make his defense.” *McNeil v. Jordan*, 814 A.2d 234, 237-38 (Pa. Super. 2002).

Defendants advance several arguments regarding the alleged deficiencies of facts and injuries, all of which are incorrect:

- Defendants assert that Plaintiffs' Complaint does not state whether the infant actually ingested the product at issue. In contrast, Plaintiffs have pled that the infant "was fed Similac and/or Enfamil cow's milk-based products" and developed NEC "after ingesting Defendant Manufacturers' products." See Ex. A Plaintiff's Second Complaint at ¶¶ 11-12.
- Defendants assert that Plaintiffs' Complaint does not indicate which product was ingested. However, Plaintiff has pled that the infant was fed the Defendant's products "Similac and/or Enfamil cow's milk-based products." *Id.* at ¶ 11. Absent discovery, Plaintiff is limited to the detail provided in the medical records, the details of which are included in Plaintiff's Complaint. As advanced previously at oral argument, Plaintiff must be allowed to conduct full discovery to determine which manufacturer and brand each Hospital system had a distribution agreement with during certain periods of time, as that information, such as brand, is not often elicited in the medical records. Further, the Defendants themselves are the ones with the information such as purchasing receipts and or purchasing agreements with either Abbott or Mead.
- Defendants argue that Plaintiffs have not met their burden under fact pleading to show that the product was unreasonably dangerous because allegedly plaintiffs' claims are "unsupported by any specific studies or trials in the Complaint." See Def. Preliminary Objections, at 8. However, as noted above, the Superior Court has ruled that in relation to pleading facts, "evidence from which such facts may be inferred not only need not but should not be alleged," which is entirely contrary to Defendants' arguments herein. See *Baker v. Rangos*, 324 A.2d 498, 505-506 (Pa. Super. 1974)
- Defendants assert that Plaintiff has not pled the period of time during which the product at issue was ingested. However, Plaintiff alleged in the Complaint that the infant "was fed Similac and/or Enfamil cow's milk-based products by [hospital staff] after her birth." *Id.* Plaintiff's birth date is included in the Complaint.
- Defendants assert that Plaintiff failed to plead when the minor was diagnosed with NEC. However, Plaintiff pled that the infant's "These feeds occurred despite the fact that Pennsylvania Hospital knew or should have known that cow's milk-based products increase the risk of NEC and that human milk can decrease the risk of NEC." *Id.* at ¶ 15. Plaintiffs averments adequately summarize the material facts necessary such that the Defendants are on notice of the claim of which they must defend, and notably the moving Defendants are the exact hospitals where the Plaintiff was initially treated for NEC, thus they have access to the exact same medical as the Plaintiffs which show the exact dates of treatment which are summarily referred to in Plaintiffs' Complaint.
- Defendants assert that Plaintiffs did not plead the treatment the infant received following the ingestion of the NEC and resulting injuries. Defendant cites no authority for the proposition that a plaintiff must describe the specific treatment an

injured party underwent following injuries resulting from the tortious conduct of a defendant.

- Defendants assert that Plaintiffs have not adequately pled the injuries suffered as a result of the product. Plaintiff has adequately pled the injuries suffered by the infant who ingested Defendant's product, specifically "As a result of Defendants' actions described infra, I.H. suffered injuries, including but not limited to, a diagnosis of NEC, treatment with surgery and resection of a portion of her bowels, short gut syndrome secondary to NEC, intestinal and feeding difficulties, neurological injuries, left lower extremity amputation at the forearm, and she continues to suffer developmental delays and feeding difficulties secondary to bowel resection and short gut syndrome." *Id.* at ¶ 22.

Accordingly, Defendant's Preliminary Objections should be overruled as Plaintiffs Allegations should withstand challenge under 1019(a) because they contain averments of all of the facts a plaintiff will eventually have to prove in order to recover, and they are sufficiently specific so as to enable Defendants to prepare their defense.

VII. Plaintiff-Parents' Claims Against Penn Medicine and HUP Are Not Time-Barred And Should Not Be Dismissed

Plaintiffs have clearly plead claims sounding in negligence on behalf of all plaintiffs, not just the injured minor plaintiff. Indeed, in the complaint, Plaintiff lists under Counts VI and VII, that "As a further direct and proximate result of Penn Medicine and Pennsylvania Hospital's negligent and reckless conduct, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries." See Plaintiffs' Complaint at ¶167, 185, 193. Therefore, Defendants no additional specificity needs to be plead as to which claims apply which Plaintiffs, and Plaintiffs' Complaint complies with Pa.R.C.P. 1020, which does not require Plaintiff Parents and Plaintiffs Minors to plead separate claims for sperate Plaintiffs as Defendant suggests.

Further, Plaintiff-parents' claims are not barred by the discovery rule on two distinct grounds. The discovery rule is an exception [to the statute of limitations] that tolls the statute of limitations when an injury or its cause is not reasonably knowable." *In re Risperdal Litig.*, 656 Pa.

649, 661 (2019). “Under the “discovery rule,” the statute of limitations begins to run when a plaintiff knows, or reasonably should have known, that: (1) an injury has been sustained; and (2) the injury has been caused by another party's conduct.” *Ward v. Rice*, 828 A.2d 1118, 1121 (Pa. Super. 2003) (citing *Citsay v. Reich*, 380 Pa. Super. 366, 369 (1988)). For the discovery rule to apply, the plaintiff must have exercised the due diligence that would be expected of a reasonable person in the plaintiff's position. 828 A.2d at 1121. A plaintiff must begin exercising reasonable diligence once they know the “the salient facts concerning the occurrence of his injury and *who or what caused it*.” *Romah v. Hygienic Sanitation Co.*, 705 A.2d 841, 857 (Pa. Super. 1997) (emphasis added). While reasonable diligence is an objective standard, “it is also flexible [...] to take into account differences between persons, their capacity to meet certain situations and circumstances confronting them at the time in question. In short, the standard of conduct required is a uniform one which takes “into account the fallibility of human beings.”” 828 A.2d at 1121-22 (quoting RST 2d § 283 cmt's b-c). Whether someone has exercised reasonable diligence “may be best determined by the collective judgment, wisdom, and experience of jurors who have been selected at random from the community whose standard is to be applied.” *Petri v. Smith*, 307 Pa. Super. 261, 271-72 (1982).

Under the discovery rule, if a plaintiff's delay is because the assurances of their physicians lull the patient into a false sense of security, this may toll the statute of limitations. *See Acker v. Palena*, 260 Pa. Super. 214, 222 (1978); *Barshady v. Schlosser*, 226 Pa. Super. 260, 263-64 (1973). The Pennsylvania Supreme Court has “expressly declined to hold, as a matter of law, that a layperson may be charged with knowledge greater than that which was communicated to her by the medical professionals who provided treatment and diagnosis.” *In re Risperdal Litig.*, 656 Pa. at 662 (citing *Wilson v. El-Daief*, 600 Pa. 161, 179-180 (2009)). If a plaintiff alleges that their

delay was due to their reasonably relying upon the reassurances of their physicians, then, while construing the pleadings in the light most favorable to the moving party, a plaintiff's claims will not be time-barred. *Acker v. Palena*, 260 Pa. Super. 214, 223-24 (1978).

Likewise, the under the similar but distinct doctrine of fraudulent concealment, a form of equitable estoppel, the statute of limitations will be tolled if a plaintiff's delay is induced by reliance on the fraudulent concealment of the defendant. *Nesbitt v. Erie Coach Co.*, 416 Pa. 89, 95-96 (1964). If, "through fraud or concealment, the defendant causes the plaintiff to relax his vigilance or deviate from his right of inquiry, the defendant is estopped from invoking the bar of the statute of limitations." *Romah*, 705 A.2d at 857 (internal quotations omitted). A defendant does not need to intentionally deceive a plaintiff for the doctrine of fraudulent concealment to apply; instead, fraudulent concealment encompasses "fraud in the broadest sense which includes an unintentional deception." 416 Pa. at 96 (citation omitted). It is for the factfinder to determine whether a defendant made representations that could have induced this reliance on the part of the plaintiff. *Id.* For example, in *Romah*, the Superior Court held that the issue of whether the plaintiff's claims for gross negligence and punitive damages were tolled because the defendant concealed studies and other information from the EPA and the public that showed that the defendant's product caused increased risk of blood cell depression in men was a factual issue for the jury. 705 A.2d at 861.

Plaintiffs have alleged that all of the medical providers that Plaintiff-parents interacted with at the Hospital failed to provide them with any information regarding the increased risk of NEC to premature infants posed by the bovine-based formula that the practitioners provided. Likewise, plaintiffs have alleged that the parents were not presented with the comparative risk of NEC of these products as compared to any other alternatives. Plaintiff-parents relied upon the

representations, or lack thereof, provided by the medical professionals who were treating their infant. Further, Plaintiff alleged that Plaintiff-parents had no medical background or training and therefore could not be expected to have greater medical knowledge than these providers. Plaintiff-parents thereby reasonably relied upon, and were lulled into a false sense of security by, the assurances of the physicians treating their children. Moreover, Plaintiff has alleged that Defendants made false representations, in line with their financially advantageous relationship that they possessed with codefendant manufacturers Abbott and Mead, about the relative risks of bovine-based formula, in order to induce reliance on the part of Plaintiff-parents and thereby conceal the true source and cause of their infant's injury. Defendant hospitals facilitated interactions between medical providers and codefendant manufacturers' sales personnel, who Defendant hospital knew would mislead medical providers about the risk of NEC posed by its products. Thus, under both the discovery rule and doctrine of fraudulent concealment, Plaintiff-parents' claims are not time-barred.

VIII. Plaintiffs Have Filed the Proper Verifications For Their Complaint

Pennsylvania Rule of Civil Procedure 1024 requires that pleadings containing averments of fact not appearing of record in the action shall state that the averment is true upon the signer's personal knowledge or information and belief and shall be verified. *See* Pa.R.C.P. 1024. Plaintiff has obtained and produced proper verification as required by the Rules. Accordingly, Defendants' objection should be overruled. All such verifications have been or will be attached by way of a praecipe to attach filed to Plaintiffs' Complaint.

IX. Request In The Alternative To Amend The Complaint

Although Plaintiff strenuously maintains the sufficiency of all of the Counts contained within the Complaint, should this Court be inclined to grant any of Defendants' specific Preliminary Objections, Plaintiff respectfully requests permission to amend the pleadings.

WHEREFORE, for the reasons more fully set forth in Plaintiff's accompanying Memorandum of Law, Plaintiff respectfully requests that this Honorable Court deny Defendants' Preliminary Objections, or, in the alternative, Order that Plaintiff is permitted leave to amend their Complaint.

Respectfully submitted,

KLINE & SPECTER,
A Professional Corporation

Date: September 3, 2024

By: /s/Timothy A. Burke, Esquire

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Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on September 3, 2024, I caused a true and correct copy of the foregoing document to be served by electronic filing to all counsel of record.

Respectfully submitted,

KLINE & SPECTER,
A Professional Corporation

Date: September 3, 2024

By: /s/Timothy A. Burke, Esquire

TIMOTHY A. BURKE, ESQUIRE

Civil Administration

Filed and Attested by the
Office of Judicial Records
18 JUL 2024 04:47 pm
S. RICE

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Defendants.

: **IN THE COURT OF COMMON PLEAS**
 : **PHILADELPHIA COUNTY**
 :
 : **CIVIL TRIAL DIVISION**
 :
 : **MARCH TERM 2022**
 : **NO. 02606**

Case ID: 220302608
Control No.: 24081574

NOTICE

You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so the case may proceed without you and a judgment may be entered against you by the court without further notice for any money claimed in the complaint or for any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW. THIS OFFICE CAN PROVIDE YOU WITH INFORMATION ABOUT HIRING A LAWYER.

IF YOU CANNOT AFFORD TO HIRE A LAWYER, THIS OFFICE MAY BE ABLE TO PROVIDE YOU WITH INFORMATION ABOUT AGENCIES THAT MAY OFFER LEGAL SERVICES TO ELIGIBLE PERSONS AT A REDUCED FEE OR NO FEE.

Lackawanna Bar Association
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ADVISOR

Le han demandado a usted en la corte. Si usted quiere defenderse de estas demandas expuestas en las paginas siguientes, usted tiene veinte (20) dias de plazo al partir de la fecha de la demanda y la notificacion. Hace falta asentar una comparencia escrita o en persona o con un abogado y entregar a la corte en forma escrita sus defensas o sus objeciones a las demandas en contra de su persona. Sea avisado que si usted no se defiende, la corte tomara medidas y puede continuar la demanda en contra suya sin previo aviso o notificacion. Ademias, la corte pueda decidir a favor del demandante y requiere que usted cumpla con todas las provisiones de esta demanda. Usted puede perder dinero o sus propiedades u otros derechos importantes para usted.

LLEVE ESTA DEMANDA A UN ABOGADO INMEDIATAMENTE, SI NO TIENE ABOGADO O SI NO TIENE EL DINERO SUFICIENTE DE PAGAR TAL SERVICIO, VAYA EN PERSONA O LLAME POR TELEFONO A LA OFICINA CUYA DIRECCION SE ENCUENTRA ESCRITA ABAJO PARA AVERIGUAR DONDE SE PUEDE CONSEGUIR ASISTENCIA LEGAL.

Colegio de Abogados del Lackawanna
233 Penn Avenue, Scranton, PA 18503
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Medicine” or “Pennsylvania Hospital”), together “Defendants.” Plaintiff alleges the following upon personal knowledge as to Plaintiff’s own acts and experiences and upon information and belief, including investigation conducted by Plaintiff’s attorneys, as to all other matters.

I. INTRODUCTION

1. This action arises out of the injuries suffered by a premature infant (the “Injured Infant”) who was given the Defendant Manufacturers’ cow’s milk-based infant feeding products at Pennsylvania Hospital. Pennsylvania Hospital, managed by Penn Medicine, acquired and supplied the Defendant Manufacturers’ products to the Injured Infant and negligently failed to warn of their unreasonably dangerous properties in a reasonable manner. This caused the Injured Infant to develop necrotizing enterocolitis (“NEC”), a life-altering and potentially deadly disease that largely affects premature babies who are given cow’s milk-based feeding products. As a result, the Injured Infant was seriously injured, resulting in long term health effects and accompanying harm to their parent (“the Plaintiff Parent”).

2. Plaintiff brings these causes of action against Defendants to recover for injuries that are the direct and proximate result of the Injured Infant’s consumption of the Defendant Manufacturers’ unreasonably dangerous cow’s milk-based infant feeding products, which were acquired and supplied without adequate warning to the Injured Infant at Pennsylvania Hospital, owned and operated by Penn Medicine.

II. PARTIES

3. Plaintiff Christina Taylor is a natural adult person and a resident of Delaware. Ms. Taylor is the parent and natural guardian of I.H., a minor. Ms. Taylor’s address is 9 Aidone Drive, New Castle, Delaware 19720.

4. Defendant Mead Johnson Nutrition Company is a corporation, incorporated under the laws

of the State of Delaware. Its principal place of business is Illinois. Defendant Mead Johnson & Company, LLC, is a limited liability company, organized under the laws of the State of Delaware. Its citizenship is that of its sole member, Mead Johnson Nutrition Company. Defendants Mead Johnson Nutrition Company and Mead Johnson & Company, LLC, (together, “Mead”) are manufacturers of cow’s milk-based infant feeding products and market many of these products under the “Enfamil” brand name.

5. Defendant Abbott Laboratories (“Abbott”) is a corporation, incorporated under the laws of the State of Illinois. Its principal place of business is in Illinois. Abbott is a manufacturer of cow’s milk-based infant feeding products and markets many of its products under the “Similac” brand name.

6. Defendant The Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital is a non-profit corporation incorporated and registered to do business under the laws of the Commonwealth of Pennsylvania. Its principal place of business is Philadelphia, Pennsylvania. Pennsylvania Hospital is a registered name of The Pennsylvania Hospital of the University of Pennsylvania Health System. The sole member of The Pennsylvania Hospital of the University of Pennsylvania Health System is The Trustees of the University of Pennsylvania.

7. Defendant The Trustees of the University of Pennsylvania d/b/a Penn Medicine is a non-profit corporation registered to do business in the Commonwealth of Pennsylvania. Its principal place of business is Philadelphia, Pennsylvania. Penn Medicine is a registered name of The Trustees of the University of Pennsylvania.

III. JURISDICTION AND VENUE

8. This Court has jurisdiction in this matter pursuant to 42 Pa. C.S.A. § 931. Defendants

conduct authorized business in the Commonwealth of Pennsylvania. They have sufficient minimum contacts with and purposefully avail themselves of the markets of this Commonwealth. This suit arises out of Defendants' forum-related activities, such that the Court of Common Pleas of Philadelphia County's exercise of jurisdiction would be consistent with traditional notions of fair play and substantial justice.

9. Venue is proper in the Court of Common Pleas of Philadelphia County pursuant to Rules 1006(b), 1006(c)(1), and 2179(a) of the Pennsylvania Rules of Civil Procedure because Defendants are corporations or similar entities that regularly conduct business in Philadelphia County, which is also the county where Plaintiff's causes of action arose, and the county where the occurrences took place out of which Plaintiff's causes of action arose.

10. This action is not subject to the Compulsory Arbitration Program of the Court of Common Pleas of Philadelphia County because the amount in controversy, excluding interest and costs, is in excess of \$50,000.

IV. FACTUAL ALLEGATIONS

I.H.'s NEC Diagnosis

11. Infant plaintiff I.H. was born premature at Pennsylvania Hospital in Philadelphia, Pennsylvania on October 9, 2010.

12. At birth, I.H.'s gestational age was approximately 25 weeks and she weighed 879 grams.

13. Starting on October 9, 2010 until November 2, 2010, I.H. was fed mother's breast milk fortified with bovine-based Human Milk Fortifier (HMF), which upon information and belief was manufactured by Defendants Abbott and/or Mead.

14. Subsequently, between November 2, 2010 and November 19, 2010 I.H. was fed full formula feeds of Abbott's Special Care 20 cal/oz or Special Care 24 cal/oz bovine-based formula.

15. These feeds occurred despite the fact that Pennsylvania Hospital knew or should have known that cow's milk-based products increase the risk of NEC and that human milk can decrease the risk of NEC.

16. On November 20, 2010, Dr. Kelly Wade of the NICU diagnosed I.H. with stage II Medical NEC after noticing I.H.'s severely distended stomach and other symptoms consistent with NEC.

17. Between November 20 and November 23, Dr. Wade attempted to treat I.H.'s NEC using antibiotics without success, and on November 23 ordered for I.H. to be emergently transferred to St. Christopher's hospital for immediate surgical evaluation.

18. Upon arrival to the St. Christopher's NICU, I.H. was diagnosed with Stage IIIB Medical NEC, the most advanced and life-threatening stage of NEC, which indicates a perforation of the infant's intestinal track.

19. On Nov 23, 2010 I.H. underwent surgical intervention at St. Christopher's, undergoing an intestinal resection of the jejunum and distal ileum, removing part of her small intestines, as well as a primary anastomosis procedure to attach the two ends of the resected bowels together. At the end of the surgery, I.H. was placed on a wound VAC to assist in healing and blood clotting.

20. Subsequent, and secondary to the surgery and wound VAC placement, necrosis spread to I.H.'s left hand and forearm, and the NICU physicians amputated I.H.'s lower left extremity from the forearm down on December 8, 2010.

21. I.H. was in patient at the St. Christopher's NICU until her discharge home on February 15, 2011.

22. As a result of Defendants' actions described *infra*, I.H. suffered injuries, including but not limited to, a diagnosis of NEC, treatment with surgery and resection of a portion of her bowels, short gut syndrome secondary to NEC, intestinal and feeding difficulties, neurological injuries,

left lower extremity amputation at the forearm, and she continues to suffer developmental delays and feeding difficulties secondary to bowel resection and short gut syndrome.

***Cow's Milk-Based Feeding Products Are Known to Cause
NEC***

23. NEC is a devastating disease that is the most frequent and lethal gastrointestinal disorder affecting preterm infants. NEC develops when harmful bacteria breach the walls of the intestine, causing portions of the intestine to become inflamed and often to die. Once NEC develops, the condition can progress rapidly from mild feeding intolerance to systemic and fatal sepsis. Up to 30 percent of NEC-diagnosed infants die from the disease.

24. Preterm and low-birth-weight infants are especially susceptible to NEC because of their underdeveloped digestive systems. Extensive scientific research, including numerous randomized controlled trials, has confirmed that cow's milk-based feeding products cause NEC in preterm and low-birth-weight infants, which in turn may lead to other medical complications, surgeries, long-term health problems, and death.

Safer, Nutritionally Superior Alternatives to Cow's Milk-Based Products Exist

25. A range of options are available that allow preterm and low-birth-weight infants to be fed exclusively human milk-based nutrition. For example, in addition to the mother's own milk, an established network delivers pasteurized donor breast milk to hospitals nationwide. Moreover, hospitals have access to shelf-stable formula and fortifiers derived from pasteurized breast milk.

26. A diet based exclusively on breast milk and breast milk fortifiers provides all the nutrition necessary to support premature and low-birth-weight infants without the elevated risk of NEC associated with cow's milk-based products.

27. The Defendant Manufacturers' products not only pose a threat to infants' health, but also displace the human milk they could otherwise receive. This displacement only increases infants'

vulnerability to NEC.

28. Human milk-based nutrition nourishes infants while creating a significantly lower risk of NEC.

29. At the time the Injured Infant was fed the Defendant Manufacturers' products, the science clearly demonstrated to Defendants that these products cause NEC and greatly increase the likelihood that a baby will develop NEC, leading to severe injury and often death.

30. Despite the scientific evidence that the Defendant Manufacturers' cow's milk-based products present a dire threat to the health and development of preterm infants, the Defendant Manufacturers have made no changes to their products or the products' packaging, guidelines, instructions, or warnings. Instead, they have continued to sell their unreasonably dangerous products. In addition, they incentivize hospitals that know the risks to use their products by providing them to the hospital for free or at a significant discount, in order that vulnerable infants and their families will become accustomed to using their products before discharge. And, in fact, the Defendant Manufacturers offer contracts to hospitals—which the hospitals accept—that actually *prevent* the health care providers from offering alternative products—even safer ones—on pain of risking the hospital's advantageous formula pricing strategy.

31. Despite the scientific evidence that the Defendant Manufacturers' cow's milk-based products present a dire threat to the health and development of preterm infants and Pennsylvania Hospital knew or should have known of that threat, staff of Pennsylvania Hospital fed Similac and/or Enfamil cow's milk-based products after her birth instead of mother's human milk and/or donor human milk.

32. Despite the scientific evidence that the Defendant Manufacturers' cow's milk-based products present a dire threat to the health and development of preterm infants and Pennsylvania

Hospital knew or should have known of that threat, staff of Pennsylvania Hospital did not properly warn Ms. Wiger of those risks and alternatives to have avoided the cow's milk-based products.

Ms. Taylor Discovers Her Claim

33. Because of the Defendants' concealment and misrepresentations, described more fully herein, Ms. Taylor did not know, and had no reason to know or suspect, that I.H.'s NEC could have been caused by the Defendant Manufacturers' products.

***Despite Exercising Diligence, a Reasonable Investigation Did Not Reveal and
Would Not Have Revealed a Factual Basis Earlier
Because Defendants Hid the Cause of NEC from Ms. Taylor***

34. Despite exercising reasonable diligence, Ms. Taylor was unable to have made the discovery earlier via a reasonable investigation because the Defendants in this litigation concealed the wrongful cause of I.H.'s injuries.

35. Amidst the physical and emotional trauma of preterm childbirth, and having her child in the neonatal intensive care unit, shortly after learning of I.H.'s NEC diagnosis, Ms. Taylor undertook an investigation into the cause of the NEC by asking the doctors the cause of her NEC.

36. The health care providers at Penn Medicine responded only that I.H. had gotten NEC because she was born premature. Penn Medicine's response did not indicate that her NEC was caused by the Defendant Manufacturers' products.

37. Not one person at Penn Medicine mentioned that the Defendant Manufacturers' formula products could have caused I.H.'s injuries. Penn Medicine's response at the time did not give Ms. Taylor any reason to suspect any wrongdoing on the part of the Defendants.

38. Ms. Taylor is a layperson with no medical background or training that would have given her any reason to doubt the response she received from her Penn Medicine health care providers at the time.

39. Given that Penn Medicine’s health care providers were in charge of the care of her newborn infant, Ms. Taylor had no reason to doubt their word.

40. Additionally, the risk of necrotizing enterocolitis was not disclosed on the labeling or packaging of *any* of the Defendant Manufacturers’ products.

41. What is more, necrotizing enterocolitis is a disease that can occur in children who are *not* fed the Defendant Manufacturers’ products, and the Defendant Manufacturers have worked to mislead parents into a false sense of security about the use of those products. Publicly disseminated materials from each Defendant Manufacturer disguise the role their products play in causing the disease—and affirmatively say, even today, that their products are safe and do not cause NEC. In fact, some publicly disseminated materials from the formula manufacturers even suggest that formula may help *reduce* the risk of this terrible and potentially fatal disease.

42. For example, Abbott’s website stays that “[t]he specific cause of NEC is unknown, but it’s most often seen in very low birth weight premature babies,” and that “about 10% of babies who are born prematurely develop NEC.” The website suggests that “new preliminary studies” suggest for the first time that “NEC prevention may . . . be possible” with the use of human milk oligosaccharides to “dramatically curb intestinal inflammation” and reduce the risk of NEC. Abbott states that these human milk oligosaccharides are found in “certain Similac formulas” although they are “not currently available in Similac’s premature infant formulas.”¹ Likewise, the website for Mead Johnson’s products states that necrotizing enterocolitis is “one of the most common and serious intestinal disease[s] among premature babies.” And it deflects responsibility

¹ The Role of HMOs in Reducing NEC, <https://www.nutritionnews.abbott/pregnancy-childhood/prenatal-breastfeeding/the-promising-role-of-hmos-in-reducing-risk-of-nec/> (last visited July 28, 2023).

from Mead Johnson’s products: “Necrotizing enterocolitis happens when tissue in the small or large intestine is injured or inflamed.”²

43. Because of the misleading information distributed by the Defendant Manufacturers, as further detailed *infra*, any research conducted by Ms. Taylor immediately after I.H.’s diagnosis, or at any time prior to seeing an advertisement, would not have led a reasonable person to suspect that the Defendant Manufacturers’ products could have caused I.H.’s injuries.

44. Ms. Taylor also did not know, and had no reason to know or suspect, that Penn Medicine breached its duty of care by distributing the Defendant Manufacturers’ products to her. Not only was Ms. Taylor unaware that the Defendant Manufacturers’ products caused I.H.’s injuries, but the Defendant Manufacturers’ distribution agreements with Penn Medicine—which allowed Penn Medicine to secure sweetheart deals for otherwise expensive premature infant formula in exchange for product placement and access to the hospital staff—were also not public or knowable to Ms. Taylor, nor could any reasonable investigation outside of litigation have uncovered the terms of those agreements.

Despite Exercising Reasonable Diligence, the Defendants’ Fraudulently Concealed the Risks of NEC from Defendant Manufacturers’ Products to Divert, Prevent, and Mislead Plaintiff Regarding the Cause of Her Child’s NEC Diagnosis

45. In addition to the averments above, the Defendants have acted in concert to fraudulently convey false and misleading information concerning the risk of NEC, and potentially death, caused by Defendant Manufacturers’ preterm infant formula products.

46. The Defendants’ actions as set forth herein constitute knowing misrepresentation, omission, suppression, and concealment of material facts, made with the intent that Plaintiff would

² Special Feeding Concerns for Preemies, <https://www.enfamil.com/articles/special-feeding-concerns-for-preemies/> (last visited July 29, 2023).

rely upon such concealment, suppression, or omission, in connection with the use of Defendants' preterm infant products.

47. Plaintiff did not know, and could not learn, the truth concerning the uses, risks and benefits of Defendant Manufacturers' preterm infant products due to Defendants' deliberate misrepresentations and concealment, suppression and omission of material facts and important information regarding the risks of NEC, and potentially death, from the products.

48. Moreover, Defendant Hospital further participated in the intentional concealment—on information and belief, it allowed the Defendant Manufacturers' sales representatives into its hospital to provide samples and free products that did not warn of their serious dangers, and to provide “education” to its NICU staff that was incomplete as to the true risks of feeding their patients the Defendant Manufacturers' products.

49. Based upon information and belief, during the relevant time period, Pennsylvania Hospital, Penn Medicine, and the Hospital of the University of Pennsylvania stocked formula products from both Abbott and Mead.

50. Additionally, Defendant Hospital failed to inform Ms. Taylor that the Defendant Manufacturers' products caused Plaintiff's NEC, even when she directly asked the cause. As noted above, after learning of Plaintiff's NEC diagnosis, Ms. Taylor was understandably concerned about the degrading health of her newborn infant. As any concerned parent would do, Ms. Taylor asked Plaintiff's health care providers at Defendant Hospital why a premature infant like I.H. was suddenly diagnosed with a terrible disease like necrotizing enterocolitis; that is, she asked Defendant Hospital what caused Plaintiff's injury. But even though Defendant Hospital knew of the increased risk of NEC from formula, it did not disclose that the formula provided to I.H. could increase the risk of NEC to preterm infants, responding only that I.H. had gotten NEC solely

because she was born premature. Not one person at the NICU mentioned that the Defendant Manufacturers' formula products could have been the cause of Plaintiff's injuries.

51. Defendant Hospital was aware that the Defendant Manufacturers' products caused NEC in premature infants. Defendant Hospital was also aware that the Defendant Manufacturers did not provide warnings on their products. However, Defendant Hospital did not warn Ms. Taylor of the risks of the products. Instead, and notwithstanding the sweetheart deal Defendant Hospital agreed to in exchange for preterm infant formula at little to no cost, Defendant Hospital repeatedly informed Ms. Taylor that it would do everything it could possibly do to keep her infant safe. Though this was clearly not true given the known risks of preterm formula for babies like I.H., it was enough for Ms. Taylor to trust that Defendant Hospital was providing preterm formula in the best interest of her child.

52. Defendants' affirmative acts of fraud and concealment, as averred herein, diverted, prevented, and/or mislead Plaintiff from discovering the medical cause of her child's NEC diagnosis.

The Defendant Manufacturers' False and Misleading Marketing Regarding Cow's Milk-Based Infant Products

53. Abbott and Mead have aggressively marketed their cow's milk-based products as medically endorsed and nutritionally equivalent alternatives to breast milk, including prior to the Injured Infant's birth.

54. Abbott's and Mead's marketing approach includes targeting the parents of preterm infants while they are still in the hospital with messages that the Defendant Manufacturers' cow's milk formulas and fortifiers are necessary for the growth and development of their vulnerable children. Often these tactics implicitly discourage mothers from breastfeeding, which reduces the mother's supply of breast milk. None of the Defendant Manufacturers' marketing materials, including their

promotional websites, reference the science showing how significantly their products increase the risk of NEC.

55. For example, upon information and belief, Mead creates information booklets for parents of premature infants to help answer some of their questions and concerns about having a premature infant in the NICU that it provides to hospitals for dissemination to parents. While Mead's booklets explain feeding options for premature infants, including formula, they do not mention that Mead's premature formula and fortifier products increase the risk of premature infants developing necrotizing enterocolitis. Instead, the booklets advise parents that sometimes a combination of breast milk and formula may be best and that premature infants will be happy and healthy or nourished and healthy regardless of whether they are receiving breast milk or formula.

56. Similarly, upon information and belief, Abbott publishes a pediatric nutrition product guide that is available online for anyone, including parents, to access wherein Abbott advises that "human milk alone does not meet all the nutritional needs of preterm infants" and that the formulations of its products, which are based on decades of research and scientific publications, are "specially designed to meet the nutritional requirements of preterm infants and can be fed with confidence to most of the preterm infants in the NICU." Nowhere in its product guide does Abbott reference that its products increase the risk of necrotizing enterocolitis.

57. Abbott also has a consumer-facing website accessible to anyone online, including parents, that specifically discusses nutrition for premature infants, wherein Abbott tells parents of premature infants that "your baby's nutrient needs are greater than what breast milk alone can provide" and that a "human milk fortifier" may be added to breastmilk to "add[] proteins, vitamins, and minerals to help support a preemie's high nutrition needs for growth and development." Nowhere in its discussion of preterm infant fortifiers or formulas does Abbott state that its products

increase the risk of necrotizing enterocolitis or that they pose more of a risk that just providing preterm infants with breast milk only. Nor does Abbott disclose that the “human milk fortifier” is actually a cow’s milk based product and not a human milk-based product, which misleads consumers.

58. Upon information and belief, both Mead and Abbott also provide materials and programs to the hospitals and the physicians and medical staff who are treating premature infants about the manufacturers’ preterm products. Upon information and belief, these materials represent that the manufacturers’ preterm products are safe and necessary for preterm infants. Mead and Abbott rely on the physicians and medical staff to not only use their products in the NICU, but to convey these messages to the parents of premature infants in their care.

59. Undoubtedly aware of the impact of their advertising, the Defendant Manufacturers, along with other formula manufacturers, are willing to spend massive sums to disseminate their message.

60. Recognizing the abuse and dangers of infant formula marketing, in 1981, the World Health Assembly—the decision-making body of the World Health Organization—developed the International Code of Marketing of Breast-milk Substitutes (“the Code”), which required companies to acknowledge the superiority of breast milk, the negative effect on breastfeeding of introducing partial bottle-feeding, and the difficulty of reversing the decision not to breastfeed. The Code also forbade advertising or other forms of promotion of formula to the general public, as well as providing sample products to mothers or members of their families.

61. While Abbott and Mead acknowledge the Code on their websites and claim to support the effort to encourage mothers to breastfeed for as long as possible, this is little more than lip service. Instead, the Defendant Manufacturers’ aggressive marketing exploits new parents’ darkest fears—

that the nutrition they are supplying to their child will not provide the best chance of survival—while wholly failing to warn that their products come with a significantly increased risk of NEC.

62. For example, Abbott’s website, on a page titled “Infant Formula Marketing,” states: “We agree with the World Health Organization that breastfeeding provides the best nutrition for babies, and we support its goal to increase breastfeeding. We also recognize that for infants who aren’t breastfed—for medical reasons or otherwise—infant formula is the only appropriate, safe alternative to meet babies’ nutritional needs.” This statement ignores the existence of donor milk, as well as human milk-based formula.

63. Abbott markets and sells multiple products specifically targeting preterm and low-birthweight infants, including Liquid Protein Fortifier, Similac NeoSure, Similac Human Milk Fortifiers, Similac Special Care 20, Similac Special Care 24, Similac Special Care 24 High Protein, and Similac Special Care 30. In advertising these products, Abbott emphasizes the products’ purported ability to assist underdeveloped babies in reaching their growth targets. For example, on the since-edited webpage regarding Similac NeoSure, Abbott noted: “Your premature baby didn’t get her full 9 months in the womb, so her body is working hard to catch up. During her first full year, feed her Similac NeoSure, a nutrient-enriched formula for babies who were born prematurely, and help support her development.” Yet, no mention was made of the accompanying significantly increased risk of NEC. At some point, the website was edited to remove this statement. However, upon information and belief, the statement remained on the website until at least December 2020.

64. Abbott’s website also contains product information and a downloadable guide for each of its products specifically targeting preterm and low-birth-weight infants, including Liquid Protein Fortifier, Similac NeoSure, Similac Human Milk Fortifiers, Similac Special Care 20, Similac

Special Care 24, Similac Special Care 24 High Protein, and Similac Special Care 30. None of these pages or guides contain any mention of NEC or that the products specifically increase the risk of NEC. Indeed, a search of Abbott’s website for “necrotizing enterocolitis” returns no hits. Instead, Abbott states that “enteral feeding” – which includes breast milk and donor milk – have been “associated with” things like “[s]pitting up, abdominal distension” or “other signs of intestinal dysfunction.” This statement is entirely misleading, as it improperly indicates that the risk of things like “spitting up” are the same for premature infants using Abbott’s products and premature infants receiving breast milk or donor milk, equates formula to non-cow’s milk-based feeding options like breast milk and donor milk, fails to mention NEC, and minimizes the risk of its products.

65. Mead markets and sells multiple products specifically targeting premature infants, including Enfamil NeuroPro EnfaCare Infant Formula, Enfamil Premature Infant Formula 24 Cal High Protein, Enfamil Premature Infant Formula 30 Cal with Iron, Enfamil Premature Infant Formula 24 Cal with Iron, Enfamil Premature Infant Formula 20 Cal with Iron, Enfamil 24 Cal Infant Formula, and Enfamil Human Milk Fortifier (acidified liquid and powder). In advertising these products, Mead emphasizes the purported similarities between its formula and breast milk, while failing to include any information about the nutritional deficits and dangers that accompany formula use. For example, the since-edited webpage for Enfamil Enfacare stated: “Premature babies fed Enfamil® formulas during the first year have achieved catch-up growth similar to that of full term, breastfed infants” and noted that Enfamil formulas include “expert-recommended levels of DHA and ARA (important fatty acids found naturally in breast milk) to support brain and eye development.”

66. One Enfamil advertisement, introducing a new product line called Enfamil NeuroPro, is entirely focused on favorably comparing Enfamil's formula to breast milk, without any mention of the product's extreme risks. Indeed, the terms "human milk" and "breast milk" are used 13 times in the advertisement, including in such statements as "for decades human milk has inspired the advancements in Enfamil formulas and now through extensive global research, we are taking an even closer look at human milk" and "only Enfamil NeuroPro has a fat blend of MFGM and DHA previously found only in breast milk." The webpage for the product has made similar manipulative claims, stating "Enfamil is backed by decades of breast milk research and multiple clinical studies" and it claims that "to create our best formulas, we collaborated on some of the most extensive breast milk studies to date[.]"

67. Mead's website also contains product information for each of its products specifically targeting preterm and low-birth-weight infants, including Enfamil NeuroPro EnfaCare Infant Formula, Enfamil Premature Infant Formula 24 Cal High Protein, Enfamil Premature Infant Formula 30 Cal with Iron, Enfamil Premature Infant Formula 24 Cal with Iron, Enfamil Premature Infant Formula 20 Cal with Iron, Enfamil 24 Cal Infant Formula, and Enfamil Human Milk Fortifier (acidified liquid and powder). None of these pages contain any mention of NEC or that the products specifically increase the risk of NEC. Indeed, a search of Mead's website for "necrotizing enterocolitis" returns no hits. Instead, Mead advertises on its website that it "has led the way in developing safe, high-quality, innovative products" – including preterm products – "to help meet the nutritional needs of infants."

68. Formula manufacturers have long used their relationships with hospitals and the discharge process to encourage parents to substitute formula for breast milk. They offer free or reduced-cost formula to hospitals for use with infants before discharge. And they offer free formula, coupons,

and even entire gift baskets to parents before their infants' discharge from the NICU or hospital.

69. Through this early targeting, the Defendant Manufacturers create brand loyalty under the guise of a “medical blessing,” in hopes that new parents continue to use formula after they leave the hospital, resulting in increased expense for parents, significantly increased risk for babies, and increased profit for the Defendant Manufacturers. The Defendant Manufacturers' giveaways and gift baskets send confusing signals to mothers who are simultaneously being encouraged to breastfeed by their healthcare professionals, and they have been shown to negatively impact breastfeeding rates.

70. Further, when the Defendant Manufacturers recognized a shift in the medical community towards an exclusive breast milk-based diet for premature infants, Abbott developed a product called “Similac Human Milk Fortifier,” and Mead developed “Enfamil Human Milk Fortifier.” These names are misleading in that they suggest that the products are derived from breast milk, when, in fact, they are cow's milk-based products. The packaging appears as:



71. The Defendant Manufacturers have designed powerful misleading marketing campaigns to deceive parents into believing that: (1) cow's milk-based products are safe, including for preterm

infants; (2) cow's milk-based products are equal, or even superior, substitutes to breast milk; (3) cow's milk-based products are necessary for proper growth and development of preterm infants; and (4) physicians consider the Defendant Manufacturers' cow's milk-based products to be a first choice. This marketing scheme is employed despite all Defendants knowing of and failing to warn of the extreme risk of NEC and death that cow's milk-based products pose to preterm infants like the Injured Infant.

72. The Defendant Manufacturers have also designed powerful marketing campaigns to both the general public and health care providers at hospitals like Pennsylvania Hospital. The Defendant Manufacturers know that sales made to hospitals are key drivers of brand loyalty, and thus are a key opportunity to drive better downstream business—*i.e.*, retail purchases by parents after they have left the hospital. On information and belief, the Defendant Manufacturers know that the formula products used in a hospital's NICU are related to getting and keeping the overall hospital contracts. And the Defendant Manufacturers know that, just like any celebrity endorsement, when mothers of newborn infants see medical professionals using a certain brand, the mothers are more likely to continue to purchase that same brand after discharge. The Defendant Manufacturers are thus heavily motivated to ensure that NICU departments are using their products.

73. Abbott and Mead Johnson focus their sales teams and training heavily on hospital NICU departments. They train their sales representatives how to increase the number of babies on their formula, and they emphasize the need to be the dominant formula manufacturer in the NICU so they can own that profitable ground and secure a great return on their substantial investment in NICU formula and other products.

74. To leverage hospitals' NICUs and secure babies in the hospital and at retail, the Manufacturer Defendants pull out all the stops to convince hospitals, including Defendant Hospital, to purchase their products. For example: Abbott and Mead Johnson provide samples of their products to hospitals for free.

75. On information and belief, to get the hospitals on board with supplying their formula for premature infants, Abbott and Mead Johnson work with hospitals to secure contracts that have special pricing discounts if a certain level of the formula-fed babies in the hospital receive just that one manufacturer's products; similar to a restaurant being a Coke or Pepsi restaurant. And notwithstanding the increased risk of the Defendant Manufacturers' products for the hospitals' most fragile patients—the preterm infants—the decision makers at these hospitals seek out these types of contracts to better the hospitals' own bottom lines.

76. On information and belief, Abbott and Mead Johnson also seek promises and/or assurances that the full range of health care providers at the hospitals, including the nurse practitioners and other staff who would pull the infant formula off the shelf, are grabbing the respective company's own formula products to give to the preterm infants. The goal of this tactic was to ensure that the Defendant Manufacturers and key people at the hospital would be sending a shared message that the preterm infant formula products were safe and without risk, even though that is not what the science said.

77. On information and belief, Abbott and Mead Johnson also seek promises and/or assurances that the full range of health care providers at the hospitals, including the nurse practitioners and other staff who would pull the infant formula off the shelf, are grabbing the respective companies' own formula products to give to the preterm infants. The goal of this tactic was to ensure that the Defendant Manufacturers and key people at the hospital would be sending a shared message that

the preterm infant formula products were safe and without risk, even though that is not what the science said.

78. On information and belief, prior to I.H.'s birth, Abbott sent sales representatives to Defendant Hospital. Those sales representatives provided information about Abbott's products to Defendant Hospital's staff via conversations, presentations, and written pamphlets. This information indicated that Abbott's products were safe to give to preterm infants like I.H. Abbott maintains call logs that detail which sales representatives visited the hospitals, which days they visited, and which products they discussed. These sales representatives did not disclose that Abbott's products could cause NEC in preterm infants.

79. On information and belief, prior to I.H.'s birth, Mead Johnson sent sales representatives to Defendant Hospital. Those sales representatives provided information about Mead Johnson's products to Defendant Hospital's staff via conversations, presentations, and written pamphlets. This information indicated that Mead Johnson's products were safe to give to preterm infants like I.H. Mead Johnson maintains call logs that detail which sales representatives visited the hospitals, which days they visited, and which products they discussed. These sales representatives did not disclose that Mead Johnson's products could cause NEC in preterm infants.

80. Mead Johnson and Abbott believed and intended that the misrepresentations that its sales representatives shared with Defendant Hospital would be used to make feeding decisions for preterm infants like I.H.

The Defendant Manufacturers' Inadequate Warnings

81. Although Mead promotes an aggressive marketing campaign designed to convince parents that its cow's milk-based products are safe and necessary for the growth of a premature infant, the product is in fact extremely dangerous for premature infants. Enfamil products significantly increase the chances of a premature infant developing potentially fatal NEC.

82. The Enfamil products Mead markets specifically for premature infants are commercially available at retail locations and online. No prescription is necessary.

83. Despite knowing of the risk of NEC, the packaging of Mead's products does not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with Mead's products, or of the magnitude of this increased risk. Mead likewise did not provide instructions or guidance for how to avoid NEC.

84. Mead cites no medical literature or research to guide the use of its products.

85. Despite knowing of the risk of NEC, Mead did not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with its products, or of the magnitude of this increased risk. Mead likewise did not provide instructions or guidance for how to avoid NEC.

86. Mead deceived the public, parents, physicians, other medical professionals, and medical staff into believing that Enfamil products were a safe and necessary alternative, supplement and/or substitute to breast milk.

87. Mead Johnson failed to provide, and continues to fail to provide, a full accounting of the risk of NEC as documented, by underrepresenting and misrepresenting the risk to the public and the medical community.

88. Despite knowing that its products were being fed to premature infants, often without the parents' informed consent, Mead failed to require or recommend that medical professionals inform parents of the significant risk of NEC or to require that parental consent be obtained prior to the products being fed to their babies. Like Mead, Abbott promotes an aggressive marketing campaign designed to make parents believe that its products are safe and necessary for the growth of premature infants, despite the products in fact being extremely dangerous for premature infants.

Abbott's products significantly increase the chances of a premature infant getting potentially fatal NEC.

89. The products Abbott markets specifically for premature infants are available at retail locations and online. No prescription is necessary.

90. Despite knowing of the risk of NEC, Abbott did not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with its products, or of the magnitude of this increased risk. Abbott likewise did not provide instructions or guidance for how to avoid NEC.

91. Abbott deceived the public, parents, physicians, other medical professionals, and medical staff into believing that its products were a safe and necessary alternative, supplement and/or substitute to breast milk.

92. Despite knowing of studies documenting an increased risk of NEC from its products, Abbott did not act to make parents or the medical community aware of those risks, and instead took steps to conceal or prevent those risks from becoming public. Despite knowing that its products were being fed to premature infants, often without the parents' informed consent, Abbott failed to require or recommend that medical professionals inform parents of the significant risk of NEC or to require that parental consent be obtained prior to the products being fed to their babies.

Penn Medicine's Failure to Warn

93. On information and belief, Penn Medicine, which operates Pennsylvania Hospital, was aware of the significantly increased risk of NEC and death associated with providing Abbott's and Mead's cow's milk-based products to its premature infant patients. It knew or should have known that feeding these cow's milk-based products can cause NEC in premature infants who otherwise would not have developed this devastating condition. It also knew or should have known that

human milk decreases the risk of NEC for premature infants. However, instead of warning of the dangers, or supplying human milk-based feeding products to preterm infants like the Injured Infant, Penn Medicine has continued to source, distribute, and supply the Defendant Manufacturers' products in its hospitals without any adequate warning. Further, the Defendant Hospital created a study putting infants, such as I.H. at great risk by providing them with bovine based formula instead of exclusive human milk-based products.

94. To that end, Penn Medicine has participated in studies designed to increase the use of donor milk while, at the same time, reducing formula feeding in neonates. The University of Pennsylvania School of Nursing, an affiliate of Penn Medicine, has conducted extensive research into the risks associated with feeding formula to premature infants. It recently partnered with the National Institute of Nursing Research to publish clinical determinations based on its experience “changing hospital systems and influencing policy,” and its findings were unequivocal:

This is what we know about the science of human milk: it reduces the risk of necrotizing enterocolitis, reduces the risk of infection, [and] creates greater enteral feed tolerance and more rapid weaning from intravenous nutrition. . . .

95. Other Penn Medicine research has similarly concluded that “[h]uman milk decreases the incidence and severity of . . . necrotizing enterocolitis (NEC).”

96. Given it was known that human milk decreases the incidence and severity of NEC, it was also known or should have been known that cows milk-based formula increases the incidence and severity of NEC.

97. Penn Medicine also purports to adhere to the tenets of the “Baby Friendly Hospital Initiative,” which seeks to increase rates of breastfeeding initiation, exclusivity, and diet duration. The “Baby Friendly Hospital Initiative” specifically targets a reduction in the rates of NEC in preterm infants by encouraging implementation of exclusive breast milk diets among new mothers. Although Pennsylvania Hospital has maintained its “Baby Friendly” designation for years, it has

not eliminated or restricted the use of formula or fortifier for preterm infants in its hospitals.

98. Given it was known since at least the early 2000s, and as far back as the 1990s, that human milk decreases the incidence and severity of NEC, it was also known or should have been known that cows milk-based formula increases the incidence and severity of NEC.

99. Penn Medicine also purports to adhere to the tenets of the “Baby Friendly Hospital Initiative,” which seeks to increase rates of breastfeeding initiation, exclusivity, and diet duration. The “Baby Friendly Hospital Initiative” specifically targets a reduction in the rates of NEC in preterm infants by encouraging implementation of exclusive breast milk diets among new mothers. Although Pennsylvania Hospital has maintained its “Baby Friendly” designation for years, it has not eliminated or restricted the use of formula or fortifier for preterm infants in its hospitals.

100. Finally, medical providers and staff at Penn Medicine have acknowledged the risks associated with providing the Defendant Manufacturers’ cow’s milk-based products to premature infant patients instead of breast milk-based nutrition. In an internal newsletter from 2012 touting donor milk programs, Penn Medicine acknowledged the benefits of a human milk-based diet, quoting a staff lactation consultant:

Donor milk is not inexpensive. It costs about \$4.25 per ounce, but the return on investment is huge. “Preemies given mother’s milk get discharged three to four days sooner and also have a six to 10 times lower risk of getting a gastrointestinal complication called necrotizing enterocolitis,” Carpenter said, adding that the infection can cost up to \$250,000 to treat. The average cost to provide a preemie with donor milk: \$125.

101. These statements demonstrate that Penn Medicine knew or should have known of the high increased risk of NEC for premature infants posed by the Defendant Manufacturers’ products.

102. Although Penn Medicine knew or should have known of the serious danger of the Defendant Manufacturers’ products, it has continued to purchase, supply, and distribute these

products to preterm infants without providing full and adequate warnings of the attendant risks to parents, healthcare professionals, and other medical staff at its relevant facilities. As a result, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products at Pennsylvania Hospital, causing their injuries. This occurred even though hospitals across the country, including Pennsylvania Hospital, warn and obtain consent from parents before providing other safer forms of nutrition, such as donor breast milk.

103. Penn Medicine's failure to warn of the risks posed by the Defendant Manufacturers' products is entrenched (and compounded) by the financial benefits it accrues from its relationships with the Defendant Manufacturers. On information and belief, it has received the Defendant Manufacturers' cow's milk-based products for free and/or at a significant discount, and has granted their sales representatives access to its healthcare professionals and medical staff. These sales representatives have provided deceptive information that Penn Medicine reasonably knew or should have known would ultimately reach parents through those staff. This arrangement dovetails with the Defendant Manufacturers' own marketing strategies" and use of salespersons.

Safer Alternative Designs

104. The Defendant Manufacturers' cow's milk-based products made specifically for premature infants are unreasonably unsafe for those infants. The Defendant Manufacturers could have used pasteurized breast milk instead of cow's milk in their products, which would have produced a safer product.

105. Prolacta Bioscience manufactures and sells breast milk-based feeding products, specifically designed for preterm infants, which contain no cow's milk. This alternative design provides all the necessary nutrition for growth and development that cow's milk-based products provide, without the same unreasonably dangerous and deadly effects.

106. On information and belief, Abbott and Mead were aware of the significantly increased risk of NEC and death associated with their cow's milk-based products, and instead of warning of the dangers, or removing them altogether, Abbott and Mead have continued to use cow's milk as the foundation of their products.

CAUSES OF ACTION
COUNT I: STRICT LIABILITY FOR DESIGN DEFECT
(Against Abbott and Mead)

107. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

108. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to manufacture, sell, and distribute their products in a manner that was not unreasonably dangerous.

109. Abbott and Mead also owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to manufacture, sell, and distribute their products in a manner that was merchantable and reasonably suited for their intended use.

110. Abbott and Mead knew that their products would be used to feed premature infants like the Injured Infant and knew (or reasonably should have known) that use of their cow's milk-based products significantly increased the risk of NEC, serious injury, and death, and that such use was therefore unreasonably dangerous to premature infants, not reasonably suited for the use intended, not merchantable, and had risks that exceeded a reasonable buyer's expectations. Nonetheless, they continued to sell and market their defective products as appropriate for premature infants.

111. The Injured Infant ingested Abbott and/or Mead's unreasonably dangerous cow's milk-based products. The risks of feeding those products to the Injured Infant outweighed the benefits. An ordinary consumer would not expect those products to carry a significant risk of serious injury

and death from NEC.

112. Abbott and Mead knew (or reasonably should have known) that breast milk-based nutrition did not carry the same risks of NEC, serious injury, and death that their products do.

113. Abbott's and Mead's products contained cow's milk at the time they left the manufacturing facility.

114. Abbott and Mead did not develop a human-milk based product that was safer for premature infants and did not reformulate their products to reduce the risk of NEC, serious injury, and death, even though doing so was economically and technologically feasible and even though pasteurized breast milk was an available alternative.

115. Abbott's and/or Mead's products were fed to the Injured Infant, which caused and/or increased the risk of their NEC and injuries.

116. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost

revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;

- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT II: STRICT LIABILITY FOR FAILURE TO WARN
(Against Abbott and Mead)**

117. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

118. Abbott and Mead, as the manufacturers and/or sellers of the infant products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide adequate warnings or instructions about the dangers and risks associated with the use of their products with preterm infants, specifically including but not limited to the risk of NEC, serious injury, and death.

119. Abbott's and Mead's duty to warn is part of their general duty to design, manufacture, and sell their infant products in a manner that is reasonably safe for their foreseeable uses. By designing their products with cow's milk-based ingredients, Abbott and Mead undertook a duty to warn of the unreasonable risk of harm posed by those ingredients, specifically including the significantly increased risk of NEC, severe injury, and death. The failure to warn makes the

products at issue in this litigation unreasonably dangerous.

120. Specifically, Abbott and Mead breached their duty to warn of the foreseeable risks of the infant products at issue in this litigation because they knew or should have known that their cow's milk-based premature infant products would be fed to premature infants like the Injured Infant, and that their products might cause the Injured Infant to develop NEC, severe injury, or death, yet they failed to provide adequate warnings of those risks. Among other risks, the Defendant Manufacturers:

- a. Failed to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death for the Injured Infant; and/or
- b. Failed to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or
- c. Inserted warnings and instructions on their products that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC and death; and/or
- d. "Black box"-type warning that their cow's milk-based products are known to significantly increase the risk of NEC and death when compared to breast milk in premature infant; and/or
- e. Failed to disclose well-researched and well-established studies that linked cow's milk-based products to NEC and death in premature infants; and/or
- f. Failed to insert a warning or instruction to healthcare professionals and other medical staff in the hospital that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed the

Defendant Manufacturers' products, notwithstanding their substantial risks; and/or

- g. Failed to provide a warning in a method reasonably calculated or expected to reach the parents of newborns, like the Plaintiff Parent; and/or
- h. Failed to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products.

121. Abbott's and Mead's products contained cow's milk at the time they left the manufacturing facility.

122. As a direct and proximate result of the inadequacy of the warnings and the pervasive marketing campaigns suggesting the safety and necessity of the Defendant Manufacturers' products, the Injured Infant were fed cow's milk-based products, which caused and/or increased risk of their developing NEC.

123. The unwarned-of risks are not of a kind that an ordinary consumer would expect. Had physicians and medical staff known of the extreme risk associated with feeding premature infants cow's milk-based formula, they would not have fed the Injured Infant those products. Had the Plaintiff Parent known of the significant risks of feeding the Injured Infant cow's milk-based formula, they would not have allowed such products to be fed to the Injured Infant.

124. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;

- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendants Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT III: NEGLIGENCE
(Against Abbott and Mead)**

125. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

126. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to exercise reasonable care to design, test, manufacture, inspect, and distribute a product free of unreasonable risk of harm to users, when such products are used in their intended manner and for their intended purpose.

127. At all times relevant to this action, the Injured Infant's healthcare professionals and medical staff used the products at issue in their intended manner and for their intended purpose.

128. Abbott and Mead, directly or indirectly, negligently, and/or defectively made, created, manufactured, designed, assembled, tested, marketed, sold, and/or distributed the cow's milk-based infant products at issue in this litigation and thereby breached their duty to the general public and the Plaintiff Parent.

129. Specifically, although Abbott and Mead knew or reasonably should have known at the time of production that their cow's milk-based infant products significantly increased the risk of NEC, serious injury, and death, they failed to act in a reasonably prudent manner and breached their duty by:

- a. Failing to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death for the Injured Infant; and/or
- b. Failing to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or
- c. Inserting warnings and instructions that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC and death; and/or
- d. Failing to insert a large and prominent "black box"-type warning that their cow's milk-based products are known to significantly increase the risk of NEC and death when compared to breast milk in premature infants; and/or
- e. Failing to provide well-researched and well-established studies that linked cow's milk-based products to NEC and death in premature infants; and/or
- f. Failing to insert a warning or instruction to healthcare professionals and other medical staff in the hospital that parents should be provided information necessary

- to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risks; and/or
- g. Failing to provide a warning in a method reasonably calculated/expected to reach the parents of newborns, like the Plaintiff Parent; and/or
- h. Failing to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products.

130. In addition, although Abbott and Mead knew or reasonably should have known at the time of production that their cow's milk-based products significantly increased the risk of NEC, serious injury, and death, they failed to act in a reasonably prudent manner and breached their duty by failing to perform the necessary process of data collection, detection, assessment, monitoring, prevention, and reporting or disclosure of adverse outcomes in infants who ingest their products.

131. As a direct and proximate result of the Defendant Manufacturers' failure to act in a reasonably prudent manner and their breach of duty, the Injured Infant was fed cow's milk-based products, which caused and/or increased the risk of their developing NEC.

132. Had Abbott and Mead satisfied their duties to the consuming public in general, the Injured Infant would not have been exposed to their unreasonably dangerous cow's milk-based products.

133. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of

life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;

- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendants Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT IV: INTENTIONAL MISREPRESENTATION
(Against Abbott and Mead)**

134. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

135. At all times relevant to this action, the Injured Infant consumed the Defendant Manufacturers' products in their intended manner and for their intended purpose.

136. Abbott and Mead, as the manufacturers and/or sellers of the infant products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide truthful, accurate, fulsome information about the risks and benefits of using their products when used in the intended manner and for the intended purpose.

137. Abbott and Mead breached their duty through misrepresentations made to consumers in their advertising and promotional materials, as described in previous paragraphs and incorporated

herein, each of whom were foreseeable and intended recipients of this information.

138. Specifically, upon information and belief, Abbott and Mead made the following false statements of material fact on an ongoing and repeated basis to the public, including patient consumers and parents like Plaintiff Parent and prior to the time the Injured Infant was fed their products:

- a. That their cow's milk-based products were safe and beneficial for premature infants when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or
- b. That their cow's milk-based products were necessary to the growth and nutrition of premature infants, when they knew or should have known that their products were not necessary to achieve adequate growth; and/or
- c. That their products have no serious side effects, when they knew or should have known the contrary to be true; and/or
- d. That cow's milk-based products were safe for premature infants; and/or
- e. That cow's milk-based products were necessary for optimum growth; and/or
- f. That cow's milk-based products were similar or equivalent to breast milk; and/or
- g. That their products were safe and more like breast milk than other infant products and that they had removed the harmful ingredients of cow's milk when, in fact, the cow's milk in their products was still capable of causing NEC, serious injury, and death; and/or
- h. That their products were safe for and provided better nutrition and growth to premature infants than donor milk, a non-cow's milk-based alternative to breast milk; and/or

- i. That their products can fed with confidence to most of the preterm infants in the NICU and/or that premature infants would be happy and health or nourished and health on their products; and/or
- j. That their products were based on up-to-date science, which made them safe for premature infants; and/or
- k. Omitting the material fact that their products significantly increased the risk of NEC in premature infants, including omitting this material fact from their publicly available product information, marketing materials, and websites.

139. Abbott and Mead had actual knowledge, or, at a minimum, a reckless indifference, to whether the aforementioned misrepresentations were false.

140. In addition to the above, Abbott and Mead, upon information and belief, also made the following false statements of material fact to Plaintiff Parent:

- a. Omitting from coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent that their products significantly increased the risk of NEC in premature infants; and/or
- b. Omitting from the packaging and labeling of their products provided to Injured Infant that their products significantly increased the risk of NEC in premature infants; and/or
- c. Representing that their cow's milk-based products were safe and beneficial for premature infants on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or

- d. Representing that their cow's milk-based products were safe and beneficial for premature infants on the packaging and labeling of their products provided to Injured Infant when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or
- e. Representing that their cow's milk-based products were necessary to the growth and nutrition of premature infants on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent when they knew or should have known that their products were not necessary to achieve adequate growth; and/or
- f. Representing that their cow's milk-based products were necessary to the growth and nutrition of premature infants on the packaging and labeling of their products provided to Injured Infant when they knew or should have known that their products were not necessary to achieve adequate growth; and/or
- g. Representing that their cow's milk-based products were similar or equivalent to breast milk on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent; and/or
- h. Representing that their cow's milk-based products were similar or equivalent to breast milk on the packaging and labeling of their products provided to Injured Infant; and/or
- i. Representing that their cow's milk-based products could be fed with confidence to premature infants and/or that premature infants would be healthy regardless of whether they were fed their cow's milk-based products or breast milk on coupons,

gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent; and/or

- j. Representing that their cow's milk-based products could be fed with confidence to premature infants and/or that premature infants would be healthy regardless of whether they were fed their cow's milk-based products or breast milk on the packaging and labeling of their products provided to Injured Infant; and/or
- k. Representing that their cow's milk-based products have no serious side effects on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent when they knew or should have known the contrary to be true; and/or
- l. Representing that their cow's milk-based products have no serious side effects on the packaging and labeling of their products provided to Injured Infant when they knew or should have known the contrary to be true; and/or
- m. Representing that their cow's milk-based products were similar or equivalent to breast milk on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent when they knew or should have known the contrary to be true; and/or
- n. Representing that their cow's milk-based products were similar or equivalent to breast milk on the packaging and labeling of their products provided to Injured Infant when they knew or should have known the contrary to be true; and/or
- o. Representing that their cow's milk-based products were safe for premature infants on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent; and/or

- p. Representing that their cow's milk-based products were safe for premature infants on the packaging and labeling of their products provided to Injured Infant; and/or
- q. Representing that their cow's milk-based products were necessary for optimum growth on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent; and/or
- r. Representing that their cow's milk-based products were necessary for optimum growth on the packaging and labeling of their products provided to Injured Infant; and/or
- s. Representing that their products were based on up-to-date science, which made them safe for premature infants on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent; and/or
- t. Representing that their products were based on up-to-date science, which made them safe for premature infants on the packaging and labeling of their products provided to Injured Infant.

141. The Plaintiff Parent was not aware that these misrepresentations were false and justifiably relied on them. The Defendant Manufacturers' misrepresentations induced the Plaintiff Parent to allow their children to be fed Abbott's and Mead's infant products, in reliance on all the messaging they received about formula feeding, including, directly or indirectly, the Defendant Manufacturers' messaging. Had Abbott and Mead not committed these intentional misrepresentations, the Injured Infant would not have been exposed to the Defendant Manufacturers' unreasonably dangerous cow's milk-based products.

142. As a direct and proximate result, Abbott's and Mead's products were fed to the Injured

Infant, which caused and/or increased risk of their developing NEC and subsequent injuries.

143. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT V: NEGLIGENT MISREPRESENTATIONS
(Against Abbott and Mead)**

144. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth

herein.

145. At all times relevant to this action, the Injured Infant consumed the products at issue in their intended manner and for their intended purpose.

146. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide truthful, accurate, and complete information about the risks and benefits of using their products when used in the intended manner and for the intended purpose.

147. In the course of their business, Abbott and Mead breached their duty through misrepresentations made to consumers, in their advertising and promotional materials, as described in previous paragraphs and incorporated herein, each of whom were foreseeable recipients of this information.

148. Specifically, upon information and belief, Abbott and Mead made the following false statements of material fact on an ongoing and repeated basis to the public, including consumers, and parents like Plaintiff Parent and prior to the time the Injured Infant was fed their products:

- a. That their cow's milk-based products were safe and beneficial for premature infants when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or
- b. That their cow's milk-based products were necessary to the growth and nutrition of premature infants, when they knew or should have known that their products were not necessary to achieve adequate growth; and/or
- c. That their products have no serious side effects, when they knew or should have known the contrary to be true; and/or
- d. That cow's milk-based products were safe for premature infants; and/or

- e. That cow's milk-based products were necessary for optimum growth; and/or
- f. That cow's milk-based products were similar or equivalent to breast milk; and/or
- g. That their products were safe and more like breast milk than other infant products and that they had removed the harmful ingredients of cow's milk when, in fact, the cow's milk in their products was still capable of causing NEC, serious injury, and death; and/or
- h. That their products were safe for and provided better nutrition and growth to premature infants than donor milk, a non-cow's milk-based alternative to breast milk; and/or
- i. That their products can be fed with confidence to most of the preterm infants in the NICU and/or that premature infants would be happy and healthy or nourished and healthy on their products; and/or
- j. That their products were based on up-to-date science, which made them safe for premature infants; and/or
- k. Omitting the material fact that their products significantly increased the risk of NEC in premature infants, including omitting this material fact from their publicly available product information, marketing materials, and websites.

149. In addition to the above, Abbott and Mead, upon information and belief, also made the following false statements of material fact to Plaintiff Parent.

- a. Omitting from coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent that their products significantly increased the risk of NEC in premature infants; and/or

- b. Omitting from the packaging and labeling of their products provided to Injured Infant that their products significantly increased the risk of NEC in premature infants; and/or
- c. Representing that their cow's milk-based products were safe and beneficial for premature infants on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or
- d. Representing that their cow's milk-based products were safe and beneficial for premature infants on the packaging and labeling of their products provided to Injured Infant when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or
- e. Representing that their cow's milk-based products were necessary to the growth and nutrition of premature infants on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent when they knew or should have known that their products were not necessary to achieve adequate growth; and/or
- f. Representing that their cow's milk-based products were necessary to the growth and nutrition of premature infants on the packaging and labeling of their products provided to Injured Infant when they knew or should have known that their products were not necessary to achieve adequate growth; and/or

- g. Representing that their cow's milk-based products were similar or equivalent to breast milk on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent; and/or
- h. Representing that their cow's milk-based products were similar or equivalent to breast milk on the packaging and labeling of their products provided to Injured Infant; and/or
- i. Representing that their cow's milk-based products could be fed with confidence to premature infants and/or that premature infants would be healthy regardless of whether they were fed their cow's milk-based products or breast milk on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent; and/or
- j. Representing that their cow's milk-based products could be fed with confidence to premature infants and/or that premature infants would be healthy regardless of whether they were fed their cow's milk-based products or breast milk on the packaging and labeling of their products provided to Injured Infant; and/or
- k. Representing that their cow's milk-based products have no serious side effects on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent when they knew or should have known the contrary to be true; and/or
- l. Representing that their cow's milk-based products have no serious side effects on the packaging and labeling of their products provided to Injured Infant when they knew or should have known the contrary to be true; and/or

- m. Representing that their cow's milk-based products were similar or equivalent to breast milk on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent when they knew or should have known the contrary to be true; and/or
- n. Representing that their cow's milk-based products were similar or equivalent to breast milk on the packaging and labeling of their products provided to Injured Infant when they knew or should have known the contrary to be true; and/or
- o. Representing that their cow's milk-based products were safe for premature infants on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent; and/or
- p. Representing that their cow's milk-based products were safe for premature infants on the packaging and labeling of their products provided to Injured Infant; and/or
- q. Representing that their cow's milk-based products were necessary for optimum growth on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent; and/or
- r. Representing that their cow's milk-based products were necessary for optimum growth on the packaging and labeling of their products provided to Injured Infant; and/or
- s. Representing that their products were based on up-to-date science, which made them safe for premature infants on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent; and/or

- t. Representing that their products were based on up-to-date science, which made them safe for premature infants on the packaging and labeling of their products provided to Injured Infant.

150. Abbott and Mead were negligent or careless in not determining those representations to be false.

151. The Defendant Manufacturers' misrepresentations induced, and were intended to induce, the Plaintiff Parent to allow their child to be fed Abbott's and Mead's infant products, in justifiable reliance on all the messaging they received about formula feeding, including, directly or indirectly, the Defendant Manufacturers' messaging. Had Abbott and Mead not committed these negligent misrepresentations, the Injured Infant would not have been exposed to their unreasonably dangerous cow's milk-based products.

152. As a direct and proximate result, Abbott's and Mead's products were fed to the Injured Infant, which caused and/or increased of their developing NEC and subsequent injuries.

153. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;

- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT VI: FAILURE TO WARN
(Against Penn Medicine and Pennsylvania Hospital)**

154. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

155. Penn Medicine and Pennsylvania Hospital as purchaser, supplier, and/or distributor of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to purchase, supply, and distribute products that were free of unreasonable risk of harm when used in their intended manner and for their intended purpose, and/or to formulate, adopt, and enforce adequate rules and policies for the same.

156. At all times relevant to this action, the Injured Infant used the cow's milk-based products purchased, supplied, and/or distributed by Penn Medicine and Pennsylvania Hospital in their intended manner and for their intended purpose.

157. Penn Medicine and Pennsylvania Hospital employed or contracted with the healthcare professionals and medical staff at Pennsylvania Hospital, managing these individuals during their

treatment of the Injured Infant.

158. Penn Medicine and Pennsylvania Hospital negligently, outrageously, and recklessly supplied and distributed the Defendant Manufacturers' milk-based infant feeding products to these healthcare professionals and medical staff for use on premature infants, including the Injured Infant.

159. Moreover, at all relevant times, Penn Medicine and Pennsylvania Hospital knowingly authorized the Defendant Manufacturers' sales representatives to market, advertise, distribute, and/or sell their products at Pennsylvania Hospital. The Defendant Manufacturers' sales representatives were encouraged to interact with Pennsylvania Hospital's healthcare professionals and medical staff. These interactions provided the Defendant Manufacturers' sales representatives an opportunity to co-opt Pennsylvania Hospital's healthcare professionals and medical staff into assisting with the marketing, distribution, and/or sale of the Defendant Manufacturers' unreasonably dangerous products to consumers, such as the Plaintiff Parent.

160. Penn Medicine and Pennsylvania also knowingly, and intentionally, allowed the Defendant Manufacturers' sales representatives to routinely misrepresent the risks and benefits of Defendants' products to Pennsylvania Hospital's healthcare professionals and medical staff, including the misrepresentation that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

161. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known at the time that they acquired, distributed, and supplied the Defendant Manufacturers' cow's milk-based infant products that these products significantly increased the risk of NEC, serious injury, and death.

162. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, outrageously,

and recklessly, and breached its duty by:

- a. Failing to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in those babies; and/or
- b. Failing to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or
- c. Failing to warn or instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risk; and/or
- d. Failing to provide its healthcare professionals and medical staff with the well-researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or
- e. Failing to provide a warning in a method reasonably calculated/expected to reach the parents of newborns; and/or
- f. Failing to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products; and/or
- g. Failing to prevent the Defendant Manufacturers' sales representatives from misrepresenting to Pennsylvania Hospital's healthcare professionals and medical staff that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

163. Reasonable hospitals under the same or similar circumstances would have warned of the above risks, would have instructed their healthcare professionals and medical staff—as well as patients—on the safe use of the Defendant Manufacturers' products, and would have restricted the

ability of the Defendant Manufacturers' sales representatives to market the Defendant Manufacturers' unreasonably dangerous products without adequate warning.

164. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that its medical professionals and the parents of premature infants, including the Plaintiff Parent, would not have realized the risks associated with feeding cow's milk-based formula to premature infants.

165. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its duty to warn its medical providers and patients about the Defendant Manufacturers' unreasonably dangerous products, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

166. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital's failure to warn of the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

167. As a further direct and proximate result of Penn Medicine and Pennsylvania Hospital's failure to warn of the Defendant Manufacturers' unreasonably dangerous products, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against Penn Medicine and Pennsylvania Hospital, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained

as a result of Penn Medicine's conduct;

- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from Penn Medicine and Pennsylvania Hospital's oppressive, outrageous, reckless, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT VII: CORPORATE LIABILITY OF HEALTH-CARE PROVIDER
(Against Penn Medicine and Pennsylvania Hospital)**

168. Plaintiff incorporates by references each of the preceding paragraphs as if fully set forth herein.

169. At all relevant times, Penn Medicine and Pennsylvania Hospital owed a duty of care to the Injured Infant to ensure their safety and well-being while the Injured Infant was under the care of Pennsylvania Hospital staff. Specifically, Penn Medicine and Pennsylvania Hospital had a duty to the Injured Infant to formulate, adopt, and enforce adequate rules and policies to ensure quality care for the Injured Infant. Further, Penn Medicine and Pennsylvania Hospital owed a duty to the Injured Infant to oversee its healthcare professionals and medical staff that provided patient care to the Injured Infant.

170. Penn Medicine and Pennsylvania Hospital owed a duty to its patients, and the Injured Infant in particular, to formulate, adopt, and enforce adequate rules and policies for the purchase, supply,

distribution, and use of products that were free of unreasonable risk of harm when used in their intended manner and for their intended purpose and ensured quality care for the Injured Infant.

171. At all times relevant to this action, the Injured Infant used the cow's milk-based products purchased, supplied, and/or distributed by Penn Medicine and Pennsylvania Hospital in their intended manner and for their intended purpose.

172. Moreover, at all relevant times, Penn Medicine and Pennsylvania Hospital knowingly authorized the Defendant Manufacturers' sales representatives to market, advertise, distribute, and/or sell their products at Pennsylvania Hospital. The Defendant Manufacturers' sales representatives were encouraged to interact with Pennsylvania Hospital's healthcare professionals and medical staff. These interactions provided the Defendant Manufacturers' sales representatives an opportunity to co-opt Pennsylvania Hospital's healthcare professionals and medical staff into assisting with the marketing, distribution, and/or sale of the Defendant Manufacturers' unreasonably dangerous products.

173. Penn Medicine and Pennsylvania Hospital also knowingly allowed the Defendant Manufacturers' sales representatives to routinely misrepresent the risks and benefits of Defendants' products to Pennsylvania Hospital's healthcare professionals and medical staff, including the misrepresentation that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

174. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known at the time that it formulated, adopted, and enforced its rules for the acquisition, distribution, and supply of the Defendant Manufacturers' cow's milk-based infant products, including the access afforded the Defendant Manufacturer's sales representatives, that these products significantly increased the risk of NEC, serious injury, and death for premature infants.

175. Since prior to 2000, Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that premature babies are increased risk for NEC.

176. Since prior to 2000, Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that NEC increases the risk of permanent injury and death.

177. Since 2000, Penn Medicine and Pennsylvania Hospital knew or reasonably should have known prior to that human milk (mother's milk) was safest and best for premature infants.

178. Since 2000, Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that human milk (mother's milk) decreased the risk of NEC, serious injury, and death for premature infants.

179. By no later than 2012, Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that donor human milk decreased the risk of NEC, serious injury, and death for premature infants.

180. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that its medical professionals and the parents of premature infants, including the Plaintiff Parent, would not have realized the risks associated with feeding cow's milk-based formula to premature infants.

181. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, outrageously, and recklessly, and breached its duty by:

- a. Failing to formulate, adopt, and enforce adequate rules and policies that would have required human milk (mother's milk and/or donor milk) to be recommended to premature babies; and/or
- b. Failing to formulate, adopt, and enforce adequate rules and policies that would have restricted or prevented the use of cow's milk-based products for feeding premature babies; and/or

- c. Failing to formulate, adopt, and enforce adequate rules and policies that informed the Plaintiff Parent that human milk (mother's milk and/or donor milk) significantly decrease the risk of NEC, severe injury, and death in premature babies, like the Injured Infant; and/or
- d. Failing to formulate, adopt, and enforce adequate rules and policies that warned the Plaintiff Parent that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in premature babies, like the Injured Infant; and/or
- e. Failing to formulate, adopt, and enforce adequate rules and policies that discussed the risks of cow's milk-based products significantly increasing the risk of NEC, severe injury, and death in premature babies, like the Injured Infant; and/or
- f. Failing to formulate, adopt, and enforce adequate rules and policies that warned its healthcare professionals and medical staff that cow's milk-based products are unsafe and/or contraindicated for premature babies like the Injured Infant; and/or
- g. Failing to formulate, adopt, and enforce adequate rules and policies to instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risk; and/or
- h. Failing to formulate, adopt, and enforce adequate rules and policies to provide its healthcare professionals and medical staff with the well-researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or
- i. Failing to formulate, adopt, and enforce adequate rules and policies to ensure a

warning in a method reasonably calculated/expected to reach the parents of premature newborns, like the Plaintiff Parent; and/or

- j. Failing to formulate, adopt, and enforce adequate rules and policies to prevent the Defendant Manufacturers' sales representative from misrepresenting to Pennsylvania Hospital's healthcare professionals and medical staff that premature babies would not grow adequately with human milk and human milk products and/or that use of donor milk was not advised for premature infants; and/or
- k. Failing to establish a donor milk program that was sufficient to meet the needs of the premature babies, like the Injured Infant.
- l. Failing to formulate, adopt, and enforce adequate rules and policies regarding the feeding of premature infants leaving it to the discretion of the medical team and parent without a discussion of risks and benefits.
- m. Allowing parental preference to be the standard for feeding premature infants;
- n. Failing to follow the American Academy of Pediatrics recommendations relating to feeding premature infants;
- o. Failing to follow the American Academy of Pediatrics recommendations to use donor milk if mother's milk was unavailable instead of cow's milk-based products;
- p. Failing to recommend donor milk if mother's milk was unavailable by no later than 2012; and
- q. Failing to transfer to a hospital by no later than 2012 where donor milk was available if there was no donor milk available.

182. A reasonable hospital under the same or similar circumstances would have formulated, adopted, and enforced adequate policies, and rules to restrict the feeding of cow's milk-based

products to premature babies, including developing an adequate donor milk program, instructing its healthcare professionals and medical staff on the safe use of Defendants Manufacturers' cow's milk-based products, and restricting the marketing of the Defendant Manufacturers' unreasonably dangerous products to its healthcare professionals, medical staff, and parents of premature infants under its care.

183. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its duty to formulate, adopt, and enforce adequate rules and policies to ensure the quality care of its patients, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

184. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital failure to formulate and enforce adequate policies and rules related to the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

185. As a further direct and proximate result of Penn Medicine and Pennsylvania Hospital negligent, reckless, and outrageous conduct the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

186. In the alternative, Penn Medicine and Pennsylvania Hospital owed a duty to its patients, and the Injured Infant in particular, to oversee the practicing healthcare professionals and medical staff that provided the products at issue to infants under Pennsylvania Hospital's care, including the Injured Infant.

187. Penn Medicine and Pennsylvania Hospital employed or contracted with the healthcare

professionals and medical staff at Pennsylvania Hospital and was responsible for overseeing those individuals during their treatment of the Injured Infant.

188. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, recklessly, and outrageously breached its duty by:

- a. Failing to oversee its healthcare professionals and medical staff on their use of cow's milk-based products for feeding premature babies; and/or
- b. Failing to warn or instruct its healthcare professionals and medical staff that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in those babies; and/or
- c. Failing to warn or instruct its healthcare professionals and medical staff that cow's milk-based products are unsafe and/or contraindicated for premature babies like the Injured Infant; and/or
- d. Failing to oversee its healthcare professionals and medical staff to restrict their feeding of cow's milk-based products to premature babies; and/or
- e. Failing to warn or instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risk; and/or
- f. Failing to provide its healthcare professionals and medical staff with the well-researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or
- g. Failing to provide its healthcare professionals and medical staff with warnings about the dangers of the Defendants' Manufacturers products in a method

reasonably calculated/expected to reach the parents of newborns; and/or

- h. Failing to provide statistical evidence to its healthcare professionals and medical staff showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products; and/or
- i. Failing to oversee its healthcare professionals and medical staff to ensure that the Defendant Manufacturers' sales representatives' misrepresentations that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants had not influenced the use and/or misuse of the Defendant Manufacturers' products.

189. A reasonable hospital under the same or similar circumstances would have warned of the above risks, would have instructed its healthcare professionals and medical staff on the safe use of the Defendant Manufacturers' products, and would have restricted the ability of the Defendant Manufacturers' sales representatives to market the Defendant Manufacturers' unreasonably dangerous products without adequate warning.

190. A reasonable hospital under the same or similar circumstances would have overseen and managed its healthcare professionals and medical staff to ensure that they received proper training and updating on the risks associated with feeding cow's milk-based formula to premature infants.

191. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its duty to oversee its healthcare professionals and medical staff who provide patient care, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

192. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital's failure to oversee its healthcare professionals and medical staff on the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the

Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

193. As a further direct and proximate result of Penn Medicine and Pennsylvania Hospital's negligent and reckless conduct, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against Penn Medicine and Pennsylvania Hospital, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of Penn Medicine and Pennsylvania Hospital's conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from Penn Medicine's oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

DEMAND FOR JURY TRIAL

194. Plaintiff hereby demands a jury trial for all claims triable.

Dated: July 16, 2024

Respectfully submitted,

KLINE & SPECTER, P.C.

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Attorneys for Plaintiffs

EXHIBIT A-69

Civil Administration

M. RIVERA

IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
TRIAL DIVISION - CIVIL

CHRISTINA TAYLOR, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	MARCH TERM, 2022 No. 220302606
TERRAINE ABDULLAH, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : : :	MARCH TERM, 2022 No. 02583
HOLLI CARTER, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : : :	MARCH TERM, 2022 No. 220302588
SHONDERA DRAYTON, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : : :	MARCH TERM, 2022 No. 02594
TONYA GRAY, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : : :	APRIL TERM, 2022 No. 220400216
ROCHELLE HOLLINGSWORTH, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : : :	SEPTEMBER TERM, 2023 No. 230900791
KRISTEN KAJUFFA, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : : :	MARCH TERM, 2022 No. 220302978

NAFEESA MAYS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	MARCH TERM, 2022 No. 220302963
CATHERINE McMILLIAN, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	APRIL TERM, 2022 No. 220400140
NYDIA PARKER, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	MARCH TERM, 2022 No. 220302983
ALEXANDRIA ROSS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	MARCH TERM, 2022 No. 220302981
LOREN SANDERS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	APRIL TERM, 2022 No. 220400153
SAMAYA SHORT, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	APRIL TERM, 2022 No. 220400159
ALICE STILLS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	MARCH TERM, 2022 No. 220302617
NATISHA THOMAS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	MARCH TERM, 2022 No. 220400158

NIKIA TUCKER, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	SEPTEMBER TERM, 2023 No. 230900867
GINA WIEGER, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	MARCH TERM, 2022 No. 220302601
STEPHANIE WILKERSON, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	SEPTEMBER TERM, 2023 No. 230900730
MELVENIA WILLIAMS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	APRIL TERM, 2022 No. 220400141

ORDER

AND NOW this the _____ day of _____, 2024, upon consideration of Defendant Mead Johnson & Company, LLC and Mead Johnson Nutrition Company's (collectively referred to as, "Mead Johnson" or "Moving Defendants") Preliminary Objections to the Plaintiffs' Complaint, Plaintiffs' Answer thereto, and all other appropriate considerations, it is hereby ORDERED, ADJUDGED and DECREED that Moving Defendants' Preliminary Objections are OVERRULED.

BY THE COURT

J.

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Attorneys for Plaintiffs

IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
TRIAL DIVISION - CIVIL

CHRISTINA TAYLOR, et al., Plaintiff,	:	
v.	:	MARCH TERM, 2022
MEAD JOHNSON & COMPANY, LLC, et al.,	:	No. 220302606
Defendants.	:	
TERRAINE ABDULLAH, et al., Plaintiff,	:	
v.	:	MARCH TERM, 2022
MEAD JOHNSON & COMPANY, LLC, et al.,	:	No. 02583
Defendants.	:	
HOLLI CARTER, et al., Plaintiff,	:	
v.	:	MARCH TERM, 2022
MEAD JOHNSON & COMPANY, LLC, et al.,	:	No. 220302588
Defendants.	:	
SHONDERA DRAYTON, et al., Plaintiff,	:	
v.	:	MARCH TERM, 2022
MEAD JOHNSON & COMPANY, LLC, et al.,	:	No. 02594
Defendants.	:	

TONYA GRAY, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : : :	APRIL TERM, 2022 No. 220400216
ROCHELLE HOLLINGSWORTH, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : : :	SEPTEMBER TERM, 2023 No. 230900791
KRISTEN KAJUFFA, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : : :	MARCH TERM, 2022 No. 220302978
NAFEESA MAYS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : : :	MARCH TERM, 2022 No. 220302963
CATHERINE McMILLIAN, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : : :	APRIL TERM, 2022 No. 220400140
NYDIA PARKER, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : : :	MARCH TERM, 2022 No. 220302983
ALEXANDRIA ROSS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : : :	MARCH TERM, 2022 No. 220302981
LOREN SANDERS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : : :	APRIL TERM, 2022 No. 220400153

SAMAYA SHORT, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	APRIL TERM, 2022 No. 220400159
ALICE STILLIS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	MARCH TERM, 2022 No. 220302617
NATISHA THOMAS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	MARCH TERM, 2022 No. 220400158
NIKIA TUCKER, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	SEPTEMBER TERM, 2023 No. 230900867
GINA WIEGER, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	MARCH TERM, 2022 No. 220302601
STEPHANIE WILKERSON, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	SEPTEMBER TERM, 2023 No. 230900730
MELVENIA WILLIAMS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	APRIL TERM, 2022 No. 220400141

**PLAINTIFFS' REPSONSE IN OPPOSITION TO MEAD JOHNSON'S PRELMINIARY
OBJECTIONS TO PLAINTIFFS' SECOND AMENDED COMPLAINTS**

Plaintiffs, by and through their counsel, Kline & Specter, P.C., hereby oppose Defendant Mead Johnson & Company, LLC and Mead Johnson Nutrition Company's (collectively referred to as, "Mead Johnson" or "Moving Defendants") Preliminary Objections and responds to Defendant's Preliminary Objections and Evidentiary Exhibits as follows:¹

1. Denied as a conclusion of law to which no response is required. By way of further response, see Plaintiffs' attached memorandum of law.
2. Denied as a conclusion of law to which no response is required. By way of further response, see Plaintiffs' attached memorandum of law.
3. Admitted.
4. Admitted only that Plaintiff has filed suits against the named defendants, denied that each complaint is identical, as each Complaint and subsequent Amended Complaints pleaded facts and damages specific to each Plaintiff and injured infant.
5. Admitted.
6. Admitted.
7. Admitted.
8. Admitted.
9. Admitted. By way of further response, see Plaintiffs' attached memorandum of law.

¹ To conserve judicial resources, and pursuant to the practice recommended by the Court at the July 24, 2023 conference, Plaintiffs file this opposition on the instant docket and incorporate by reference the arguments herein in each of the following actions in which plaintiffs filed second amended complaints: *Abdullah v. Mead Johnson & Company, LLC, et al.*, No. 220302583; *Carter v. Mead Johnson & Company, LLC, et al.*, No. 220302588; *Drayton v. Mead Johnson & Company, LLC, et al.*, No. 220302594; *Gray v. Mead Johnson & Company, LLC, et al.*, No. 220400216; *Hollingsworth v. Mead Johnson & Company, LLC, et al.*, No. 230900791; *Kajuffa v. Mead Johnson & Company, LLC, et al.*, No. 220302978; *Mays v. Mead Johnson & Company, LLC, et al.*, No. 220302963; *McMillian v. Mead Johnson & Company, LLC, et al.*, No. 220400140; *Parker v. Mead Johnson & Company, LLC, et al.*, No. 220302981; *Ross v. Mead Johnson & Company, LLC, et al.*, No. 220302981; *Sanders v. Mead Johnson & Company, LLC, et al.*, No. 220400153; *Short v. Mead Johnson & Company, LLC, et al.*, No. 220400159; *Stills v. Mead Johnson & Company, LLC, et al.*, No. 220302617; *Taylor v. Mead Johnson & Company, LLC, et al.*, No. 220302606; *Thomas v. Mead Johnson & Company, LLC, et al.*, No. 220400158; *Tucker v. Mead Johnson & Company, LLC, et al.*, No. 230900867; *Wieger v. Mead Johnson & Company, LLC, et al.*, No. 220302601; *Wilkerson v. Mead Johnson & Company, LLC, et al.*, No. 230900730; and *Williams v. Mead Johnson & Company, LLC, et al.*, No. 220400141.

10. Admitted.
11. Admitted.
12. This is an incorporation paragraph to which no response is required.
13. Denied as a conclusion of law to which no response is required. By way of further response, see Plaintiffs' attached memorandum of law.
14. Denied as a conclusion of law to which no response is required. By way of further response, see Plaintiffs' attached memorandum of law.
15. Denied as a conclusion of law to which no response is required. By way of further response, see Plaintiffs' attached memorandum of law.
16. Denied as a conclusion of law to which no response is required. By way of further response, see Plaintiffs' attached memorandum of law.
17. Denied as a conclusion of law to which no response is required. By way of further response, see Plaintiffs' attached memorandum of law.
18. Denied as a conclusion of law to which no response is required. By way of further response, see Plaintiffs' attached memorandum of law.
19. Denied as a conclusion of law to which no response is required. By way of further response, see Plaintiffs' attached memorandum of law.
20. Denied as a conclusion of law to which no response is required. By way of further response, see Plaintiffs' attached memorandum of law.
21. Denied as a conclusion of law to which no response is required. By way of further response, see Plaintiffs' attached memorandum of law.
22. Denied as a conclusion of law to which no response is required. By way of further response, see Plaintiffs' attached memorandum of law.

23. Denied as a conclusion of law to which no response is required. By way of further response, see Plaintiffs' attached memorandum of law.

24. Denied as a conclusion of law to which no response is required. By way of further response, see Plaintiffs' attached memorandum of law.

25. Denied as a conclusion of law to which no response is required. By way of further response, see Plaintiffs' attached memorandum of law.

26. Denied as a conclusion of law to which no response is required. By way of further response, see Plaintiffs' attached memorandum of law.

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33. Denied as a conclusion of law to which no response is required. By way of further response, see Plaintiffs' attached memorandum of law.

34. Denied as a conclusion of law to which no response is required. By way of further response, see Plaintiffs' attached memorandum of law.

35. Denied as a conclusion of law to which no response is required. By way of further response, see Plaintiffs' attached memorandum of law.

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38. Denied as a conclusion of law to which no response is required. By way of further response, see Plaintiffs' attached memorandum of law.

39. Denied as a conclusion of law to which no response is required. By way of further response, see Plaintiffs' attached memorandum of law.

40. Denied as a conclusion of law to which no response is required. By way of further response, see Plaintiffs' attached memorandum of law.

41. Denied as a conclusion of law to which no response is required. By way of further response, see Plaintiffs' attached memorandum of law.

42. Denied as a conclusion of law to which no response is required. By way of further response, see Plaintiffs' attached memorandum of law.

43. Denied. By way of further response, see Plaintiffs' attached memorandum of law.

44. Denied as a conclusion of law to which no response is required. By way of further response, see Plaintiffs' attached memorandum of law.

45. Denied as a conclusion of law to which no response is required. By way of further response, see Plaintiffs' attached memorandum of law.

46. Denied as a conclusion of law to which no response is required. By way of further response, see Plaintiffs' attached memorandum of law.

47. Denied as a conclusion of law to which no response is required. By way of further response, see Plaintiffs' attached memorandum of law.

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52. Denied as a conclusion of law to which no response is required. By way of further response, see Plaintiffs' attached memorandum of law.

53. Denied as a conclusion of law to which no response is required. By way of further response, see Plaintiffs' attached memorandum of law.

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68. Denied as a conclusion of law to which no response is required. By way of further response, see Plaintiffs' attached memorandum of law.

69. Denied as a conclusion of law to which no response is required. By way of further response, see Plaintiffs' attached memorandum of law.

70. Denied as a conclusion of law to which no response is required. By way of further response, see Plaintiffs' attached memorandum of law.

71. Denied as a conclusion of law to which no response is required. By way of further response, see Plaintiffs' attached memorandum of law.

WHEREFORE, for the reasons more fully set forth in Plaintiffs' accompanying Memorandum of Law, Plaintiffs respectfully request that this Honorable Court deny Defendant's Preliminary Objections, or, in the alternative, Order that Plaintiffs are permitted leave to amend their Complaint.

Respectfully submitted,

KLINE & SPECTER,
A Professional Corporation

Date: September 3, 2024

By: /s/Timothy A. Burke, Esquire

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Attorneys for Plaintiffs

IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY
 FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
 TRIAL DIVISION - CIVIL

CHRISTINA TAYLOR, et al.,	:	
Plaintiff,	:	
v.	:	MARCH TERM, 2022
MEAD JOHNSON & COMPANY, LLC, et al.,	:	No. 220302606
Defendants.	:	
<hr/>		
TERRAINE ABDULLAH, et al.,	:	
Plaintiff,	:	
v.	:	MARCH TERM, 2022
MEAD JOHNSON & COMPANY, LLC, et al.,	:	No. 02583
Defendants.	:	
<hr/>		
HOLLI CARTER, et al.,	:	
Plaintiff,	:	
v.	:	MARCH TERM, 2022
MEAD JOHNSON & COMPANY, LLC, et al.,	:	No. 220302588
Defendants.	:	
<hr/>		
SHONDERA DRAYTON, et al.,	:	
Plaintiff,	:	
v.	:	MARCH TERM, 2022
MEAD JOHNSON & COMPANY, LLC, et al.,	:	No. 02594
Defendants.	:	

TONYA GRAY, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : : :	APRIL TERM, 2022 No. 220400216
ROCHELLE HOLLINGSWORTH, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : : :	SEPTEMBER TERM, 2023 No. 230900791
KRISTEN KAJUFFA, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : : :	MARCH TERM, 2022 No. 220302978
NAFEESA MAYS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : : :	MARCH TERM, 2022 No. 220302963
CATHERINE McMILLIAN, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : : :	APRIL TERM, 2022 No. 220400140
NYDIA PARKER, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : : :	MARCH TERM, 2022 No. 220302983
ALEXANDRIA ROSS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : : :	MARCH TERM, 2022 No. 220302981
LOREN SANDERS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : : :	APRIL TERM, 2022 No. 220400153

SAMAYA SHORT, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	APRIL TERM, 2022 No. 220400159
ALICE STILLS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	MARCH TERM, 2022 No. 220302617
NATISHA THOMAS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	MARCH TERM, 2022 No. 220400158
NIKIA TUCKER, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	SEPTEMBER TERM, 2023 No. 230900867
GINA WIEGER, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	MARCH TERM, 2022 No. 220302601
STEPHANIE WILKERSON, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	SEPTEMBER TERM, 2023 No. 230900730
MELVENIA WILLIAMS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	APRIL TERM, 2022 No. 220400141

**PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF THEIR RESPONSE IN
OPPOSITION TO MEAD JOHNSON'S PRELIMINARY OBJECTIONS TO
PLAINTIFFS' SECOND AMENDED COMPLAINTS**

I. Matter Before the Court

Plaintiffs, by and through their counsel, Kline & Specter, P.C., hereby oppose Defendant Mead Johnson & Company, LLC and Mead Johnson Nutrition Company's (collectively referred to as, "Mead Johnson" or "Moving Defendants") Preliminary Objections and respond to the Moving Defendants' Preliminary Objections and Evidentiary Exhibits as follows:²

II. Counter Statement of Questions Involved

1. Whether this Honorable Court should deny Defendant's Preliminary Objections as to Plaintiffs' Counts I-V where Plaintiffs have adequately plead and alleged that bovine-based formula is unreasonably dangerous and substantially increases the risk for the development of NEC in preterm infants, and where Plaintiffs are not required under the pleading standard to cite to evidence (such as any medical studies) in their Complaint in support of ultimate issues that will have to be proven at trial?

Suggested answer in the affirmative.

2. Whether this Honorable Court should deny Defendant's Preliminary Objections as to Plaintiffs' strict liability claims (Counts I and II) where Plaintiffs' claims are properly plead and legally sufficient?

Suggested answer in the affirmative.

² To conserve judicial resources, and pursuant to the practice recommended by the Court at the July 24, 2023 conference, Plaintiffs file this opposition on the instant docket and incorporate by reference the arguments herein in each of the following actions in which plaintiffs filed second amended complaints: *Abdullah v. Mead Johnson & Company, LLC, et al.*, No. 220302583; *Carter v. Mead Johnson & Company, LLC, et al.*, No. 220302588; *Drayton v. Mead Johnson & Company, LLC, et al.*, No. 220302594; *Gray v. Mead Johnson & Company, LLC, et al.*, No. 220400216; *Hollingsworth v. Mead Johnson & Company, LLC, et al.*, No. 230900791; *Kajuffa v. Mead Johnson & Company, LLC, et al.*, No. 220302978; *Mays v. Mead Johnson & Company, LLC, et al.*, No. 220302963; *McMillian v. Mead Johnson & Company, LLC, et al.*, No. 220400140; *Parker v. Mead Johnson & Company, LLC, et al.*, No. 220302983; *Ross v. Mead Johnson & Company, LLC, et al.*, No. 220302981; *Sanders v. Mead Johnson & Company, LLC, et al.*, No. 220400153; *Short v. Mead Johnson & Company, LLC, et al.*, No. 220400159; *Stills v. Mead Johnson & Company, LLC, et al.*, No. 220302617; *Taylor v. Mead Johnson & Company, LLC, et al.*, No. 220302606; *Thomas v. Mead Johnson & Company, LLC, et al.*, No. 220400158; *Tucker v. Mead Johnson & Company, LLC, et al.*, No. 230900867; *Wieger v. Mead Johnson & Company, LLC, et al.*, No. 220302601; *Wilkerson v. Mead Johnson & Company, LLC, et al.*, No. 230900730; and *Williams v. Mead Johnson & Company, LLC, et al.*, No. 220400141.

3. Whether this Honorable Court should deny Defendant's Preliminary Objections as to Plaintiffs' negligence claim (Count III) where Plaintiffs' claim is properly plead and legally sufficient.

Suggested answer in the affirmative.

4. Whether this Honorable Court should deny Defendant's Preliminary Objections as to Plaintiffs' negligent misrepresentation claims (Counts IV and V) where Plaintiffs' claim is properly plead and legally sufficient?

Suggested answer in the affirmative.

5. Whether this Honorable Court should deny Defendant's Preliminary Objections as to Plaintiffs' Amended Complaint where Plaintiff has adequately pleaded all necessary facts and damages to allow for Defendants to prepare their defense to Plaintiffs' claims?

Suggested answer in the affirmative.

6. Whether this Honorable Court should deny Defendants Preliminary Objections as to the Plaintiff Parents claims for Negligent Infliction of Emotional Distress where those claims are tolled and therefore not barred by the statute of limitations?

Suggested answer in the affirmative.

7. Whether this Honorable Court should deny Defendants Preliminary Objections as to Plaintiffs' Punitive Damages claims in Counts I through V of the Amended Complaint where Plaintiffs have adequately plead conduct which is sufficiently plead and adequate for a subsequent finding by a jury for Punitive Damages?

Suggested answer in the affirmative.

8. Whether this Honorable Court should deny Defendants Preliminary Objections where Plaintiffs' necessary verifications have been filed and/or are being filed by way of a praecipe to attach to Plaintiffs' Second Amended Complaints?

Suggested answer in the affirmative.

III. Plaintiff has Adequately Plead That Defendant's Products Are Unreasonably Dangerous

Defendant asserts that Plaintiff's Amended Complaint fails to plead that Defendant's products are "unreasonably dangerous." Defendant is incorrect in this assertion, and their Preliminary Objections should be overruled.

Defendant's Preliminary Objections on this argument seem to rely heavily on their distrust of the science cited by Plaintiff regarding the dangers of their products. This argument is inappropriate at the Preliminary Objections stage. Rather, a complaint must only give a defendant only fair notice of the plaintiff's claims and a summary of the material facts that support those claims. Pa. R.C.P. 1019(a). In arguing that Plaintiffs' studies cited in their amended complaint are somehow inadequate to show the product is unreasonably dangerous, Defendants fail to realize that Pennsylvania law does require Plaintiffs to support any pleadings with evidence to pass preliminary objection. Indeed, the Superior Court has previously held that "[e]vidence from which such facts [alleged in a complaint] may be inferred not only need not but should not be alleged. Allegations will withstand challenge under 1019(a) if (1) they contain averments of all of the facts a plaintiff will eventually have to prove in order to recover, and (2) they are sufficiently specific so as to enable defendant to prepare his defense." *Baker v. Rangos*, 324 A.2d 498, 505-506 (Pa. Super. 1974) (citations and internal quotations omitted)(emphasis added).

Further, in assessing whether particular paragraphs in a complaint satisfy this requirement, they must be read in context with all other allegations in the complaint to determine whether the

defendant has been provided adequate notice of the claim against which it must defend. *Yacoub v. Lehigh Valley Med. Associates, P.C.*, 805 A.2d 579, 589 (Pa. Super. Ct. 2002). When determining whether certain allegations are sufficiently specific, Pennsylvania Law requires that the allegation be read in the context of the entire Complaint and not in a vacuum. *Hook v. L.B. Smith, Inc.*, 69 D&C 2d 420 (1974); *Duchess Underwear Co. V. Sivan Manuf. Co.*, 75 D&C 185 (1950); accord *Cmwlt h v. Bell Tel Co.*, 121 Pa. Cmwlt h 642, 649, 551 A2d 602 (1988). The Court must determine “whether the complaint is sufficiently clear to enable the Defendant to prepare his defense or [if it] informs the Defendant with accuracy and 3 completeness of the specific basis on which recovery is sought so that he may know without question upon what grounds to make his defense.” *McNeil v. Jordan*, 814 A.2d 234, 237-38 (Pa. Super. 2002).

Defendant’s assertion that Plaintiffs’ Amended Complaints are “devoid of any facts showing” Defendant’s products are “unreasonably dangerous” is patently incorrect. Plaintiffs’ Amended Complaint includes dozens of paragraphs explaining the dangers of Defendant’s product.

In determining whether a product is “unreasonably dangerous,” the Court must consider seven factors:

- (1) The usefulness and desirability of the product—its utility to the user and to the public as a whole.
- (2) The safety aspects of a product—the likelihood that it will cause injury, and the probable seriousness of the injury.
- (3) The availability of a substitute product which would meet the same need and not be as unsafe.
- (4) The manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility.
- (5) The user's ability to avoid danger by the exercise of care in the use of the product.
- (6) The user's anticipated awareness of the dangers inherent in the product and their avoidability, because of general public knowledge

of the obvious condition of the product, or of the existence of suitable warnings or instructions.

(7) The feasibility on the part of the manufacturer, of spreading the loss of setting the price of the product or carrying liability insurance.

Riley v. Warren Mfg., Inc., 688 A.2d 221, 225 (1997). The Court need not make a finding on all seven factors to determine that a product is unreasonably dangerous. *Id.*

Here, Plaintiffs' Second Amended Complaints have adequately pled that the products at issue are unreasonably dangerous. For example, Plaintiff's Second Amended Complaint includes an entire section titled "**Cow's Milk-Based Feeding Products Are Known to Cause NEC.**" Further, Plaintiff pleads that there is an "elevated risk of NEC associated with cow's milk-based products" and that "the science clearly demonstrated to Defendants that these products cause NEC and greatly increase the likelihood that a baby will develop NEC, leading to severe injury and often death." See Ex. A, Plaintiffs' Second Amended Complaint in *McMillian*, at ¶¶ 21-30. Further, as relates the user's awareness of the danger, Plaintiffs' Complaints details how Defendant, including through their product labels, failed to warn doctor and parents of the increased risk of NEC. Finally, Plaintiff's Complaint details several safer alternative designs that also speak to the manufacturer's ability to eliminate the danger, including donor breast milk, pasteurized breast milk, breast milk fortifiers, and breast milk-based products designed for pre-term infants. *Id.* at ¶¶ 23-30, 103-105.

Defendant cites *Orange Stones Co. v. City of Reading*, a case involving violation of an ordinance by a business in support of its contentions that Plaintiffs have not adequately plead that their products are unreasonably dangerous. There, the party filing preliminary objections claimed that plaintiff's complaint was deficient because it provided no facts to support its contention that the defendant acted "maliciously," "without probable cause," and "with the specific intent. *Orange Stones Co. v. City of Reading*, 87 A.3d 1014, 1025 (Pa. Commw. Ct. 2014). The trial court

sustained the preliminary objections, agreeing that the plaintiff had pled no facts to support this contention. *Id.* at 10126. Thus, the Court reasoned, these contentions were “bald assertions.” *Id.*

Here, the instant Plaintiffs’ allegations are not merely bald assertions. As discussed above, Plaintiffs have pled dozens of paragraphs to support their contention that the products at issue are “unreasonably dangerous” and specifically plead that medical studies show that feeding preterm infants cow’s milk-based formula, as opposed to human breast milk (donor or otherwise), substantially increases the risk of them developing NEC and possibly dying or being otherwise seriously injured. Accordingly, because Plaintiffs’ Amended Complaint adequately pleads that Defendant’s products are unreasonably dangerous, Defendant’s Preliminary Objections should be denied.

IV. Plaintiffs’ Amended Complaints Have Adequately Identified The Products At Issue For Both Their Product Liability and Negligence Claims

Defendant asserts that Plaintiff’s Second Amended Complaint fails to identify the product at issue. Defendant is wrong and their Preliminary Objections should be overruled.

A complaint must give a defendant only fair notice of the plaintiff’s claims and a summary of the material facts that support those claims. Pa. R.C.P. 1019(a). In assessing whether particular paragraphs in a complaint satisfy this requirement, they must be read in context with all other allegations in the complaint to determine whether the defendant has been provided adequate notice of the claim against which it must defend. *Yacoub v. Lehigh Valley Med. Associates, P.C.*, 805 A.2d 579, 589 (Pa. Super. Ct. 2002). When determining whether certain allegations are sufficiently specific, Pennsylvania Law requires that the allegation be read in the context of the entire Complaint and not in a vacuum. *Hook v. L.B. Smith, Inc.*, 69 D&C 2d 420 (1974); *Duchess Underwear Co. V. Sivan Manuf. Co.*, 75 D&C 185 (1950); accord *Cmwlth v. Bell Tel Co.*, 121 Pa. Cmwlth 642, 649, 551 A2d 602 (1988). The Court must determine “whether the complaint is

sufficiently clear to enable the Defendant to prepare his defense or [if it] informs the Defendant with accuracy and completeness of the specific basis on which recovery is sought so that he may know without question upon what grounds to make his defense.” *McNeil v. Jordan*, 814 A.2d 234, 237-38 (Pa. Super. 2002).

Plaintiff has clearly and adequately identified the product that caused the injury at issue to the best of their ability at this time. Specifically, Plaintiff pled that the infant was fed the Defendants’ specific “Similac and/or Enfamil cow’s milk-based products.” *See* Plaintiffs’ Amended Complaint at ¶ 13. Absent discovery on the supply of each particular brand to each particular hospital, Plaintiff is limited to the detail provided in the medical records and the Plaintiff parents recollection, all of which are included in Plaintiffs’ Second Amended Complaints. In the Second Amended Complaints, where evidence of the particular brand of formula exists after a preliminary review of the available medical records, Plaintiffs have included the exact formula and amounts given in the amended Complaints. *See e.g. Ex A, McMillian v. Mead Johnson, et al; see also Ex. B, Taylor v. Abbott Laboratories, et al.* Additionally, there are certain cases among the 19 existing NEC coordinated cases which clearly evidence of both Abbott and Mead formula products being administered to the injured infants prior to diagnosis with NEC. *See Ex. C, Short v. Abbott Laboratories, Mead Johnson, et al.*

Further, in almost all of the Second Amended Complaints, Plaintiff adduced evidence that in addition to being fed formula in the NICU, injured infants were often also fed bovine based human milk fortifier, the brand of which is not always recorded in the medical records. Deposition evidence taken in this case has shown that both Abbott and Mead products were stocked on the shelves of Defendant hospital’s shelves at various times, and discovery on supply issues is still ongoing in this litigation. Therefore, were the medical records themselves do not evidence which

brand of forum and or fortifier was used, Plaintiff have pleaded that the fortifier was Abbott and/or Mead based upon evidence that both were in supply at various times.

As advanced previously at oral argument, Plaintiffs must be allowed to conduct full discovery to determine which of the two manufacturers' brand of cow's milk-based formula each Hospital system had a supply agreement with during certain periods of time, as that information, such as the formula brand, is not often elicited in the medical records. In fact, the hospital Defendants themselves are the ones with the best access to the information needed such as purchasing receipts and or purchasing agreements with either Abbott or Mead.

Defendant cites *Cummins v. Firestone Tire & Rubber Co.* in support of their position that Plaintiffs have not adequately identified the product at issue. 495 A.2d 963 (Pa. Super. Ct. 1985). In *Cummins*, preliminary objections were sustained because the “**manufacturer or seller**” could not be determined, *even if the plaintiff were afforded discovery*. *Id.* at 968. Here, the manufacturer or seller is identified in Plaintiff's Complaint, the products at issue are also identified, and discovery will likely reveal even further detail about those products and which brand was fed to the Plaintiff during certain period of time, namely around the birth of each Plaintiff. As such, Defendant's Preliminary Objections should be overruled.

V. Plaintiff Has Adequately Pled the Facts and Damages at Issue

Defendant asserts that Plaintiffs' Amended Complaints fail to adequately plead facts regarding liability and injuries claimed. Defendant is wrong and their Preliminary Objections should be overruled. A complaint must give a defendant fair notice of the plaintiff's claims and a summary of the material facts that support those claims. Pa. R.C.P. 1019(a). As the Superior Court has noted:

Rule 1019(a) requires fact pleading. The purpose of 1019(a) is to require the pleader to disclose the material facts **sufficient to enable the adverse party to prepare**

his case. A complaint therefore must do more than give the defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests. It should formulate the issues by fully summarizing the material facts. Material facts are ultimate facts, i.e., those facts essential to support the claim. **Evidence from which such facts may be inferred not only need not but should not be alleged.** Allegations will withstand challenge under 1019(a) if (1) they contain averments of all of the facts a plaintiff will eventually have to prove in order to recover, and (2) they are sufficiently specific so as to enable defendant to prepare his defense.

Baker v. Rangos, 324 A.2d 498, 505-506 (Pa. Super. 1974) (citations and internal quotations omitted)(emphasis added).

In assessing whether particular paragraphs in a complaint satisfy this requirement, they must be read in context with all other allegations in the complaint to determine whether the defendant has been provided adequate notice of the claim against which it must defend. *Yacoub v. Lehigh Valley Med. Associates, P.C.*, 805 A.2d 579, 589 (Pa. Super. Ct. 2002). When determining whether certain allegations are sufficiently specific, Pennsylvania Law requires that the allegation be read in the context of the entire Complaint and not in a vacuum. *Hook v. L.B. Smith, Inc.*, 69 D&C 2d 420 (1974); *Duchess Underwear Co. V. Sivan Manuf. Co.*, 75 D&C 185 (1950); accord *Cmwlth v. Bell Tel Co.*, 121 Pa. Cmwlth 642, 649, 551 A2d 602 (1988). The Court must determine “whether the complaint is sufficiently clear to enable the Defendant to prepare his defense or [if it] informs the Defendant with accuracy and completeness of the specific basis on which recovery is sought so that he may know without question upon what grounds to make his defense.” *McNeil v. Jordan*, 814 A.2d 234, 237-38 (Pa. Super. 2002).

Defendants advance several arguments regarding the alleged deficiencies of facts and injuries, all of which are incorrect:

- Defendants assert that Plaintiffs’ Amended Complaint does not state whether the infant actually ingested the product at issue. In contrast, Plaintiffs have pled that the infant “was fed Similac and/or Enfamil cow’s milk-based products” and developed NEC “after ingesting Defendant Manufacturers’ products.” See Ex. A, Plaintiff’s Second Amended Complaint in *McMillian* at ¶¶ 11-20.

- Defendants assert that Plaintiffs' Amended Complaint does not indicate which product was ingested. However, Plaintiff has pled that the infant was fed the Defendant's products "Similac and/or Enfamil cow's milk-based products...After birth, T.M. was made NPO, with no feedings until day of life (DOL) 2, when formula feeds and breastmilk fortified with 'EPF24' were started. These feeds continued until November 19, when the NIC-U physician's orders were changed to continuous feeds of exclusively 'EPF24.' Based upon information and belief, "EPF24" is Enfamil Preterm Formula 24 cal/oz, a Mead Johnson product which is a bovine milk based formula." See Ex. A, Plaintiff's Second Amended Complaint in *McMillian* at ¶¶ 11-20. Absent discovery, Plaintiff is limited to the detail provided in the medical records, the details of which are included in Plaintiff's Complaint. As advanced previously at oral argument, Plaintiff must be allowed to conduct full discovery to determine which manufacturer and brand each Hospital system had a distribution agreement with during certain periods of time, as that information, such as brand, is not often elicited in the medical records. Further, the Defendants themselves are the ones with the information such as purchasing receipts and or purchasing agreements with either Abbott or Mead.
- Defendants argue that Plaintiffs have not met their burden under fact pleading to show that the product was unreasonably dangerous because allegedly plaintiffs' claims are "unsupported by any specific studies or trials in the Amended Complaint." See Def. Preliminary Objections. However, as noted above, the Superior Court has ruled that in relation to pleading facts, "evidence from which such facts may be inferred not only need not but should not be alleged," which is entirely contrary to Defendants' arguments herein. See *Baker v. Rangos*, 324 A.2d 498, 505-506 (Pa. Super. 1974)
- Defendants assert that Plaintiff has not pled the period of time during which the product at issue was ingested. However, Plaintiff alleged in the Complaint that the infant "was fed Similac and/or Enfamil cow's milk-based products by [hospital staff] after her birth." *Id.* Plaintiff's birth date is included in the Complaint.
- Defendants assert that Plaintiff failed to plead when the minor was diagnosed with NEC. However, Plaintiff pled that the infant's "diagnosis of NEC occurred during [the infant's] course of treatment at Defendant Hospital's NICU." *Id.* at ¶ 11-20. Plaintiffs' averments adequately summarize the material facts necessary such that the Defendants are on notice of the claim of which they must defend, and notably the moving Defendants are the exact hospitals where the Plaintiff was initially treated for NEC, thus they have access to the exact same medical as the Plaintiffs which show the exact dates of treatment which are summarily referred to in Plaintiffs' Amended Complaint.
- Defendants assert that Plaintiffs did not plead the treatment the infant received following the ingestion of the NEC and resulting injuries. Defendant cites no authority for the proposition that a plaintiff must describe the specific treatment an

injured party underwent following injuries resulting from the tortious conduct of a defendant.

- Defendants assert that Plaintiffs have not adequately pled the injuries suffered as a result of the product. Plaintiff has adequately pled the injuries suffered by the infant who ingested Defendant's product, specifically "As a result of the Medical NEC diagnosis and associated treatment, infant T.M. experienced permanent developmental delay, including neurodevelopmental delay" *Id.* at ¶ 20.

Accordingly, Defendant's Preliminary Objections should be overruled as Plaintiffs Allegations should withstand challenge under 1019(a) because they contain averments of all of the facts a plaintiff will eventually have to prove in order to recover, and they are sufficiently specific so as to enable Defendants to prepare their defense.

VI. Plaintiffs Have Plead Their Intentional and Negligent Misrepresentation Claims With Adequate Specificity, They Therefore Should Not Be Dismissed

The requirements of Pennsylvania's rules as to the sufficiency of pleadings with relation to a misrepresentation claim are satisfied if a plaintiff pleads facts sufficient to permit defendants to prepare a defense. *Commonwealth v. National Apartment Leasing Company*, 108 Pa.Commonwealth Ct. 300, 529 A.2d 1157 (1987); *see also McGinn v. Valloti*, 363 Pa.Superior Ct. 88, 525 A.2d 732 (1987); *see also Foster v. Peat Marwick Main & Co.*, 138 Pa. Cmwlth. 147, 156, 587 A.2d 382, 387 (1991), *aff'd sub nom. Foster v. Mut. Fire, Marine & Inland Ins. Co.*, 544 Pa. 387, 676 A.2d 652 (1996). Here, when the complaint is examined in its entirety, it clearly describes a course of conduct alleged to be fraudulent or misrepresentative sufficient to notify Abbott for purposes of defending the claim. *See National Apartment Leasing, supra*. In fact, Plaintiffs devote several pages of their Second Amended Complaints to facts describing the misrepresentation conduct of Defendant Mead wherein they allege, inter alia, that:

Prior to [Plaintiff's] birth, Mead sent sales representatives to Defendant Hospital. Those sales representatives provided information about Mead's products to Defendant Hospital's staff via conversations, presentations, and written pamphlets. **This information indicated that Mead's products were**

safe to give to preterm infants like [Plaintiffs]. Mead maintains call logs that detail which sales representatives visited the hospitals, which days they visited, and which products they discussed. **These sales representatives did not disclose that Mead's products could cause NEC in preterm infants...** Mead Johnson and Mead believed and intended that the misrepresentations that its sale representatives shared with Defendant Hospital would be used to make feeding decisions for preterm infants like [Plaintiff]... **Despite knowing of the risk of NEC, Mead did not warn of the significantly increased risk of NEC** (and resulting medical conditions, and/or death) associated with its products, or of the magnitude of this increased risk. Mead likewise did not provide instructions or guidance for how to avoid NEC.

See Plaintiffs' Amended Complaint, at ¶¶ 60-62, 72 (emphasis added).

Further, after instruction from the Court to expand upon their misrepresentation claims through amendment of their complaints, the Plaintiffs have added the following factual averments to their amended complaints in support of their misrepresentation claims in ¶¶ 51-79:

53. For example, upon information and belief, Mead creates information booklets for parents of premature infants to help answer some of their questions and concerns about having a premature infant in the NICU that it provides to hospitals for dissemination to parents. While Mead's booklets explain feeding options for premature infants, including formula, they do not mention that Mead's premature formula and fortifier products increase the risk of premature infants developing necrotizing enterocolitis. Instead, the booklets advise parents that sometimes a combination of breast milk and formula may be best and that premature infants will be happy and healthy or nourished and healthy regardless of whether they are receiving breast milk or formula.

...

56. Upon information and belief, both Mead and Abbott also provide materials and programs to the hospitals and the physicians and medical staff who are treating premature infants about the manufacturers' preterm products. Upon information and belief, these materials represent that the manufacturers' preterm products are safe and necessary for preterm infants. Mead and Abbott rely on the physicians and medical staff to not only use their products in the NICU, but to convey these messages to the parents of premature infants in their care.

...

65. Mead's website also contains product information for each of its products specifically targeting preterm and low-birth-weight infants, including Enfamil NeuroPro EnfaCare Infant Formula, Enfamil Premature Infant Formula 24 Cal High Protein, Enfamil Premature Infant Formula 30 Cal with Iron, Enfamil Premature Infant Formula 24 Cal with Iron, Enfamil Premature Infant Formula 20 Cal with Iron, Enfamil 24 Cal Infant Formula,

and Enfamil Human Milk Fortifier (acidified liquid and powder). None of these pages contain any mention of NEC or that the products specifically increase the risk of NEC. Indeed, a search of Mead's website for "necrotizing enterocolitis" returns no hits. Instead, Mead advertises on its website that it "has led the way in developing safe, high-quality, innovative products" – including preterm products – "to help meet the nutritional needs of infants."

See Ex. A, Taylor v. Abbott, et al. Second Amended Complaint, at ¶¶ 53-79.

Further, Plaintiffs have since amended their Complaints to include the following allegations in Counts IV and Count V of their Complaints, starting in Count IV at ¶¶ 137 and 139, and repeated for Count V at 147 and 148:

147. Specifically, upon information and belief, Abbott and Mead made the following false statements of material fact on an ongoing and repeated basis to the public, including consumers, and parents like Plaintiff Parent and prior to the time the Injured Infant was fed their products:

- a. That their cow's milk-based products were safe and beneficial for premature infants when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or
- b. That their cow's milk-based products were necessary to the growth and nutrition of premature infants, when they knew or should have known that their products were not necessary to achieve adequate growth; and/or
- c. That their products have no serious side effects, when they knew or should have known the contrary to be true; and/or
- d. That cow's milk-based products were safe for premature infants; and/or
- e. That cow's milk-based products were necessary for optimum growth; and/or
- f. That cow's milk-based products were similar or equivalent to breast milk; and/or
- g. That their products were safe and more like breast milk than other infant products and that they had removed the harmful ingredients of cow's milk when, in fact, the cow's milk in their products was still capable of causing NEC, serious injury, and death; and/or
- h. That their products were safe for and provided better nutrition and growth to premature infants than donor milk, a non-cow's milk-based alternative to breast milk; and/or
- i. That their products can be fed with confidence to most of the preterm infants in the NICU and/or that premature infants would be happy and healthy or nourished and health on their products; and/or
- j. That their products were based on up-to-date science, which made them safe for premature infants; and/or

- k. Omitting the material fact that their products significantly increased the risk of NEC in premature infants, including omitting this material fact from their publicly available product information, marketing materials, and websites.
148. In addition to the above, Abbott and Mead, upon information and belief, also made the following false statements of material fact to Plaintiff Parent.
- a. Omitting from coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent that their products significantly increased the risk of NEC in premature infants; and/or
 - b. Omitting from the packaging and labeling of their products provided to Injured Infant that their products significantly increased the risk of NEC in premature infants; and/or
 - c. Representing that their cow's milk-based products were safe and beneficial for premature infants on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or
 - d. Representing that their cow's milk-based products were safe and beneficial for premature infants on the packaging and labeling of their products provided to Injured Infant when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or
 - e. Representing that their cow's milk-based products were necessary to the growth and nutrition of premature infants on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent when they knew or should have known that their products were not necessary to achieve adequate growth; and/or
 - f. Representing that their cow's milk-based products were necessary to the growth and nutrition of premature infants on the packaging and labeling of their products provided to Injured Infant when they knew or should have known that their products were not necessary to achieve adequate growth; and/or
 - g. Representing that their cow's milk-based products were similar or equivalent to breast milk on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent; and/or
 - h. Representing that their cow's milk-based products were similar or equivalent to breast milk on the packaging and labeling of their products provided to Injured Infant; and/or
 - i. Representing that their cow's milk-based products could be fed with confidence to premature infants and/or that premature infants would be healthy regardless of whether they were fed their cow's milk-based products or breast milk on coupons, gift bags, other promotional materials, and the

packaging and labeling of their product samples provided to Plaintiff Parent; and/or

- j. Representing that their cow's milk-based products could be fed with confidence to premature infants and/or that premature infants would be healthy regardless of whether they were fed their cow's milk-based products or breast milk on the packaging and labeling of their products provided to Injured Infant; and/or
- k. Representing that their cow's milk-based products have no serious side effects on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent when they knew or should have known the contrary to be true; and/or
- l. Representing that their cow's milk-based products have no serious side effects on the packaging and labeling of their products provided to Injured Infant when they knew or should have known the contrary to be true; and/or
- m. Representing that their cow's milk-based products were similar or equivalent to breast milk on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent when they knew or should have known the contrary to be true; and/or
- n. Representing that their cow's milk-based products were similar or equivalent to breast milk on the packaging and labeling of their products provided to Injured Infant when they knew or should have known the contrary to be true; and/or
- o. Representing that their cow's milk-based products were safe for premature infants on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent; and/or
- p. Representing that their cow's milk-based products were safe for premature infants on the packaging and labeling of their products provided to Injured Infant; and/or
- q. Representing that their cow's milk-based products were necessary for optimum growth on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent; and/or
- r. Representing that their cow's milk-based products were necessary for optimum growth on the packaging and labeling of their products provided to Injured Infant; and/or
- s. Representing that their products were based on up-to-date science, which made them safe for premature infants on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent; and/or
- t. Representing that their products were based on up-to-date science, which made them safe for premature infants on the packaging and labeling of their products provided to Injured Infant.

See Ex. A, *McMillian v. Mead Johnson, et al.* Second Amended Complaint, at ¶¶ 137-39, 147-48.

Clearly, Plaintiffs have articulated their two misrepresentation claims with sufficient particularity to allow for Defendant Abbott to have adequate notice of their claim and know the material facts such that they can formulate a defense. As seen above, Plaintiffs' Amended Complaint states 1) the misrepresentations of safety that were relayed by Abbott, 2) that those misrepresentations were made by Abbott to the to the Plaintiff Parents, 3) who then relied upon the misrepresentation of safety to decide what formula to allow to be fed to their children, and finally 4) that Abbott was aware of the potential for their formula to cause NEC prior to the misrepresentations being made. Defendants' arguments that Plaintiffs have failed to articulate what misrepresentations were made such that they can adequately form a defense are spurious, and their preliminary objections should be summarily denied.

VII. Plaintiffs' Complaint Sufficiently Alleges that Defendant Consciously Disregarded the Risks Posed by the Products that they Manufactured, Distributed, and Sold Absent Adequate Warnings, Supporting Punitive Damages

Punitive damages may be awarded for "conduct that is outrageous, because of the defendant's evil motive or his reckless indifference to the rights of others." *Hutchison v. Luddy*, 582 Pa. 114, 121 (2005) (quoting *Feld v. Merriam*, 506 Pa. 383, 395 (1984)). Punitive damages must be based on conduct that is "wanton," "willful," or "reckless." 582 Pa. at 121. As such, in Pennsylvania, to survive preliminary objections, a plaintiff must allege that (1) a defendant had a subjective appreciation of the risk of harm to which the plaintiff was exposed and that (2) he acted, or failed to act, as the case may be, in conscious disregard of that risk. *Id.* For instance, in *Engle v. BT Indus. AB*, 41 Pa. D. & C.4th 25, 26, 33-34 (Pa.C.P. 1999), plaintiffs brought a products liability suit based on the manufacturers' negligence, strict liability claims, and breach of warranty. The defendant's motion to strike the plaintiff's punitive damages claim was denied. In denying the

defendant's motion, the Court stated that the "plaintiff has alleged that the defendants introduced a defective product into the stream of commerce with the knowledge of defects and the possible harm that they would cause. Such conduct, if proven, may well be interpreted as exhibiting the type of reckless indifference that may trigger punitive damages." *Id.* Hence, when a manufacturer has a subjective appreciation of the risk of harm posed by a product, and then introduces said product into the stream of commerce regardless, this conduct may rise to the level of conscious disregard required to warrant punitive damages. Further, to the extent that there is any doubt about whether the standard for punitive damages is met, that doubt must be resolved in the Plaintiff's favor at this stage. See *Theodore v. Del. Valley Sch. Dist.*, 575 Pa. 321, 333 (2003).

Plaintiffs have alleged that Abbott and Mead knowingly distributed a product that they knew posed an extreme danger to infants for profit. Abbott and Mead knew that the bovine-based products they supplied posed an increased risk of NEC, an extremely serious disease which can cause death, to premature infants, as compared to other economically and technologically feasible alternatives, such as human nutrition-based alternatives. Instead, Abbott and Mead chose to continue to produce bovine-based products, marketing them specifically towards pre-term infants, and not formulate alternatives that they knew would reduce the risk of NEC to premature infants. Hence, Abbott and Mead knowingly produced products that they knew could cause harm to infants and chose to place them into the stream of commerce, in some cases marketing those products for use with pre-term infants, in conscious disregard of the risk posed to infants.

Abbott and Mead also knew that the ordinary consumer would not expect these products to pose an increased risk of NEC and despite this, failed to warn consumers about the increased risk of NEC posed by their bovine-based products. Plaintiff alleges that Abbott and Mead failed to provide warnings to consumers that adequately and thoroughly described the increased risk of

NEC posed by their products, as demonstrated by significant scientific evidence, in a way that was reasonably calculated to communicate these risks to parents of infants. Similarly, this failure to disclose substantial risks and communicate them in a way that would adequately inform parents was knowing and intentional conduct on the part of Abbott and Mead that evinces a conscious disregard of the risk posed by their products. Therefore, these allegations rise to the level of conscious disregard required to justify the issue of punitive damages proceeding at this stage.

VIII. Plaintiff-Parents' Claims Against Defendants Are Not Time-Barred And Should Not Be Dismissed

Defendants' Preliminary Objections should be denied because Plaintiff's negligent infliction of emotional distress ("NIED") claim, brought under the bystander theory of liability, conforms with Pennsylvania legal precedent. Plaintiff-Parents contemporaneously observed a traumatic event injuring their child which satisfies the requisite element of an NIED claim.

Under Pennsylvania law, a plaintiff may pursue a claim for NIED in four different situations: "(1) where the defendant had a contractual or fiduciary duty toward the plaintiff; (2) where the plaintiff was subjected to a physical impact; (3) where the plaintiff was in a zone of danger, thereby reasonably experiencing a fear of impending physical injury; or (4) where the plaintiff observed a tortious injury to a close relative." *Toney v. Chester County Hosp.*, 961 A.2d 192, 197–98 (Pa. Super. 2008), *aff'd*, 36 A.3d 83 (Pa. 2011). The fourth scenario—the "bystander" theory of liability—arises where the plaintiff's distress is a foreseeable result of witnessing a loved one's injury. *See Sinn v. Burd*, 404 A.2d 672, 686 (Pa. 1979).

Based on the precedent set forth in *Sinn v. Burd*, Pennsylvania courts permit a plaintiff to recover for NIED as a "bystander" if the plaintiff's injury was reasonably foreseeable in light of three factors: "(1) whether plaintiff was located near the scene of the accident as contrasted with one who was a distance away from it, (2) whether the shock resulted from a direct emotional

impact upon plaintiff from the sensory and contemporaneous observance of the accident, as contrasted with learning of the accident from others after its occurrence, and (3) whether plaintiff and the victim were closely related, as contrasted with an absence of any relationship or the presence of only a distant relationship.” *Sinn*, 404 A.2d at 685 (quoting *Dillon v. Legg*, 441 P.2d 912, 920 (Cal. 1968)). To prevail, the plaintiff must show some form of “discrete and identifiable traumatic event” which caused the plaintiff’s distress. *Turner v. Med. Ctr., Beaver, PA, Inc.*, 686 A.2d 830, 832–33 (Pa. Super. 1996) (quoting *Love v. Cramer*, 606 A.2d 1175, 1177 (Pa. Super. 1992)). While interpreting *Sinn*, the Pennsylvania Superior Court has held the definition of “sensory and contemporaneous observance” depends on “whether the emotional shock was immediate and direct rather than distant and indirect, and not upon the sense employed in seeing the accident.” *Krysmalski by Krysmalski v. Tarasovich*, 622 A.2d 298, 303 (Pa. Super. 1993). The plaintiff alleging NIED must also assert a physical manifestation of the emotional harm. *See Banyas v. Lower Bucks County Hospital*, 437 A.2d 1236, 1239–40 (Pa. Super. 1981).

Here, Plaintiff has satisfied all prongs of the “bystander” theory of NIED. First, they were physically present to witness the severely deteriorated and near-death state of their child resulting from Defendants’ negligence. Second, Plaintiffs’ shock was a direct emotional impact from their contemporaneous observance of their child in the hospital. Finally, Plaintiffs and their child are obviously closely related. Plaintiffs’ emotional distress from this negligence was completely foreseeable and has resulted in physical manifestations including depression and other harms.

In their Preliminary Objections, Defendants argue that Plaintiff did not assert a specific cause of action. However, Defendants fail to recognize it is well-settled Pennsylvania law that a complaint that contains facts that support a specific cause of action does, in fact, assert said action. *Bartanus v. Lis*, 480 A.2d 1178, 1182 (Pa. Super. 1984) (ruling that “[e]ven though appellant did

not separate his factual allegations into separate counts specifying the legal theories underlying the complaint, the trial court was obligated to consider what causes of action were supported by the facts alleged” because “the complainant need only state the material facts upon which a cause of action is based”).

Pennsylvania is a fact pleading state whereby the Complaint must provide defendants with notice of the basis of the claim and a summary of the facts essential to support that claim. *Alpha Tau Omega Fraternity*, 464 A.2d at 1352. Under the Pennsylvania Rules of Civil Procedure, a complainant must list the material facts underlying his claim “in a concise and summary form.” Pa.R.C.P. 1019(a); see *Thompson Coal Co. v. Pike Cole Co.*, 412 A.2d 466, 468 (Pa. 1979).

When read in the context of the Complaint as a whole, as required by law, Plaintiff clearly asserts an NIED claim. Notably, Plaintiff includes extensive factual allegations in paragraphs eleven (11) through eighty-two (82), the entirety of which must be considered when interpreting every other paragraph of the Complaint. See Plaintiff’s Complaint at 11–82. Within those extensive factual allegations, the “bystander” theory of liability is clearly asserted as the plaintiff-parents’ distress is a foreseeable result of witnessing the injury of their child resulting from Defendants’ negligence. See *Sinn v. Burd*, 404 A.2d 672, 686 (Pa. 1979).

In sum, Plaintiff’s NIED claim under a “bystander” theory of liability is sufficiently pled. Plaintiffs were physically present to witness the severely deteriorated and near-death state of their child resulting from Defendants’ negligence. There was a direct emotional impact from this contemporaneous observance of their child in the hospital.

Further, Plaintiff-parents’ claims are not time-barred because Defendant Mead prevented Plaintiff-parents from learning the true cause of their infant’s injury. The discovery rule is an exception [to the statute of limitations] that tolls the statute of limitations when an injury or its

cause is not reasonably knowable.” In re Risperdal Litig., 656 Pa. 649, 661 (2019). “Under the “discovery rule,” the statute of limitations begins to run when a plaintiff knows, or reasonably should have known, that: (1) an injury has been sustained; and (2) the injury has been caused by another party's conduct.” *Ward v. Rice*, 828 A.2d 1118, 1121 (Pa. Super. 2003) (citing *Citsay v. Reich*, 380 Pa. Super. 366, 369 (1988)). For the discovery rule to apply, the plaintiff must have exercised the due diligence that would be expected of a reasonable person in the plaintiff's position. 828 A.2d at 1121. A plaintiff must begin exercising reasonable diligence once they know the “the salient facts concerning the occurrence of his injury and who or what caused it.” *Romah v. Hygienic Sanitation Co.*, 705 A.2d 841, 857 (Pa. Super. 1997) (emphasis added). While reasonable diligence is an objective standard, “it is also flexible [...] to take into account differences between persons, their capacity to meet certain situations and circumstances confronting them at the time in question. In short, the standard of conduct required is a uniform one which takes “into account the fallibility of human beings.”” 828 A.2d at 1121-22 (quoting RST 2d § 283 cmt's b-c). Whether someone has exercised reasonable diligence “may be best determined by the collective judgment, wisdom, and experience of jurors who have been selected at random from the community whose standard is to be applied.” *Petri v. Smith*, 307 Pa. Super. 261, 271-72 (1982).

Under the discovery rule, if a plaintiff's delay is because the assurances of their physicians lull the patient into a false sense of security, this may toll the statute of limitations. See *Acker v. Palena*, 260 Pa. Super. 214, 222 (1978); *Barshady v. Schlosser*, 226 Pa. Super. 260, 263-64 (1973). The Pennsylvania Supreme Court has “expressly declined to hold, as a matter of law, that a layperson may be charged with knowledge greater than that which was communicated to her by the medical professionals who provided treatment and diagnosis.” In re Risperdal Litig., 656 Pa.

at 662 (citing *Wilson v. El-Daief*, 600 Pa. 161, 179-180 (2009)). If a plaintiff alleges that their delay was due to their reasonably relying upon the reassurances of their physicians, then, while construing the pleadings in the light most favorable to the moving party, a plaintiff's claims will not be time-barred. *Acker v. Palena*, 260 Pa. Super. 214, 223-24 (1978).

Likewise, the under the similar but distinct doctrine of fraudulent concealment, a form of equitable estoppel, the statute of limitations will be tolled if a plaintiff's delay is induced by reliance on the fraudulent concealment of the defendant. *Nesbitt v. Erie Coach Co.*, 416 Pa. 89, 95-96 (1964). If, "through fraud or concealment, the defendant causes the plaintiff to relax his vigilance or deviate from his right of inquiry, the defendant is estopped from invoking the bar of the statute of limitations." *Romah*, 705 A.2d at 857 (internal quotations omitted). A defendant does not need to intentionally deceive a plaintiff for the doctrine of fraudulent concealment to apply; instead, fraudulent concealment encompasses "fraud in the broadest sense which includes an unintentional deception." *Nesbitt, supra*, 416 Pa. at 96 (citation omitted). It is for the factfinder to determine whether a defendant made representations that could have induced this reliance on the part of the plaintiff. *Id.* For example, in *Romah*, the Superior Court held that the issue of whether the plaintiff's claims for gross negligence and punitive damages were tolled because the defendant concealed studies and other information from the EPA and the public that showed that the defendant's product caused increased risk of blood cell depression in men was a factual issue for the jury. *Romah, supra*, 705 A.2d at 861.

Plaintiffs have alleged that manufacturers Abbott and Mead took numerous steps to prevent Plaintiff-parents from learning the cause of their infant's injuries. Defendants disseminated materials to the public that intentionally misled parents about the risk of NEC posed by their products, which affirmatively stated, and still state, that their products do not cause the disease, or

worse still, may reduce the risk of NEC. For instance, Mead published numerous misleading statements on its publicly available website that misrepresented the link between its bovine-based formula and the risk of NEC in premature infants. In addition, Defendant manufacturers trained and directed its sales personnel to mislead medical providers about the risk of NEC posed by its products. Further, Defendant manufacturers did not provide warnings on their packaging or products, thereby also concealing the known risk of NEC from parents. Thus, under both the discovery rule and doctrine of fraudulent concealment, Plaintiff-parents' claims are not time-barred.

IX. Plaintiffs Have Filed the Proper Verifications For Their Amended Complaints

Pennsylvania Rule of Civil Procedure 1024 requires that pleadings containing averments of fact not appearing of record in the action shall state that the averment is true upon the signer's personal knowledge or information and belief and shall be verified. *See* Pa.R.C.P. 1024. Plaintiff has obtained and produced proper verification as required by the Rules. Accordingly, Defendants' objection should be overruled. All such verifications have been and/or will immediately be attached by way of a praecipe to attach filed to Plaintiffs' Amended Complaint.

X. Request In The Alternative To Amend The Complaint

Although Plaintiff strenuously maintains the sufficiency of all of the Counts contained within the Complaint, should this Court be inclined to grant any of Defendants' specific Preliminary Objections, Plaintiff respectfully requests permission to amend the pleadings.

WHEREFORE, for the reasons more fully set forth in Plaintiff's accompanying Memorandum of Law, Plaintiff respectfully requests that this Honorable Court deny Defendants' Preliminary Objections, or, in the alternative, Order that Plaintiff is permitted leave to amend their Complaint.

Respectfully submitted,

KLINE & SPECTER,
A Professional Corporation

Date: September 3, 2024

By: /s/Timothy A. Burke, Esquire

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TOBI MILLROOD, ESQUIRE
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Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on September 3, 2024, I caused a true and correct copy of the foregoing document to be served by electronic filing to all counsel of record.

Respectfully submitted,

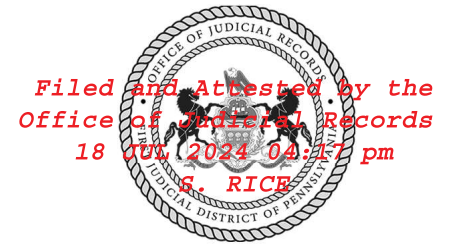
KLINE & SPECTER,
A Professional Corporation

Date: September 3, 2024

By: /s/Timothy A. Burke, Esquire

TIMOTHY A. BURKE, ESQUIRE

FILED
03 SEP 2024 04:47 pm
Civil Administration
M. RIVERA



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CHRISTINA TAYLOR, on her own behalf and as
Parent and Natural Guardian of I.H., a Minor,

Plaintiff,

v.

MEAD JOHNSON & COMPANY, LLC, MEAD
JOHNSON NUTRITION COMPANY, ABBOTT
LABORATORIES, THE TRUSTEES OF THE
UNIVERSITY OF PENNSYLVANIA d/b/a PENN
MEDICINE, and THE TRUSTEES OF THE
UNIVERSITY OF PENNSYLVANIA d/b/a
PENNSYLVANIA HOSPITAL,

Defendants.

: **IN THE COURT OF COMMON PLEAS**
: **PHILADELPHIA COUNTY**
:
: **CIVIL TRIAL DIVISION**
:
: **MARCH TERM 2022**
: **NO. 02606**

NOTICE TO DEFEND

<p>NOTICE</p> <p>You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so the case may proceed without you and a judgment may be entered against you by the court without further notice for any money claimed in the complaint or for any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.</p> <p>YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW. THIS OFFICE CAN PROVIDE YOU WITH INFORMATION ABOUT HIRING A LAWYER.</p> <p>IF YOU CANNOT AFFORD TO HIRE A LAWYER, THIS OFFICE MAY BE ABLE TO PROVIDE YOU WITH INFORMATION ABOUT AGENCIES THAT MAY OFFER LEGAL SERVICES TO ELIGIBLE PERSONS AT A REDUCED FEE OR NO FEE.</p> <p>Lackawanna Bar Association 233 Penn Avenue Scranton, PA 18503 (570) 961-2714</p>	<p>ADVISO</p> <p>Le han demandado a usted en la corte. Si usted quiere defenderse de estas demandas expuestas en las paginas siguientes, usted tiene veinte (20) dias de plazo al partir de la fecha de la demanda y la notificacion. Hace falta asentar una comparencia escrita o en persona o con un abogado y entregar a la corte en forma escrita sus defensas o sus objeciones a las demandas en contra de su persona. Sea avisado que si usted no se defiende, la corte tomara medidas y puede continuar la demanda en contra suya sin previo aviso o notificacion. Ademias, la corte pueda decidir a favor del demandante y requiere que usted cumpla con todas las provisiones de esta demanda. Usted puede perder dinero o sus propiedades u otros derechos importantes para usted.</p> <p>LLEVE ESTA DEMANDA A UN ABOGADO INMEDIATAMENTE, SI NO TIENE ABOGADO O SI NO TIENE EL DINERO SUFICIENTE DE PAGAR TAL SERVICIO, VAYA EN PERSONA O LLAME POR TELEFONO A LA OFICINA CUYA DIRECCION SE ENCUENTRA ESCRITA ABAJO PARA AVERIGUAR DONDE SE PUEDE CONSEGUIR ASISTENCIA LEGAL.</p> <p>Colegio de Abogados del Lackawanna 233 Penn Avenue, Scranton, PA 18503 (570) 961-2714</p>
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Medicine” or “Pennsylvania Hospital”), together “Defendants.” Plaintiff alleges the following upon personal knowledge as to Plaintiff’s own acts and experiences and upon information and belief, including investigation conducted by Plaintiff’s attorneys, as to all other matters.

I. INTRODUCTION

1. This action arises out of the injuries suffered by a premature infant (the “Injured Infant”) who was given the Defendant Manufacturers’ cow’s milk-based infant feeding products at Pennsylvania Hospital. Pennsylvania Hospital, managed by Penn Medicine, acquired and supplied the Defendant Manufacturers’ products to the Injured Infant and negligently failed to warn of their unreasonably dangerous properties in a reasonable manner. This caused the Injured Infant to develop necrotizing enterocolitis (“NEC”), a life-altering and potentially deadly disease that largely affects premature babies who are given cow’s milk-based feeding products. As a result, the Injured Infant was seriously injured, resulting in long term health effects and accompanying harm to their parent (“the Plaintiff Parent”).

2. Plaintiff brings these causes of action against Defendants to recover for injuries that are the direct and proximate result of the Injured Infant’s consumption of the Defendant Manufacturers’ unreasonably dangerous cow’s milk-based infant feeding products, which were acquired and supplied without adequate warning to the Injured Infant at Pennsylvania Hospital, owned and operated by Penn Medicine.

II. PARTIES

3. Plaintiff Christina Taylor is a natural adult person and a resident of Delaware. Ms. Taylor is the parent and natural guardian of I.H., a minor. Ms. Taylor’s address is 9 Aidone Drive, New Castle, Delaware 19720.

4. Defendant Mead Johnson Nutrition Company is a corporation, incorporated under the laws

of the State of Delaware. Its principal place of business is Illinois. Defendant Mead Johnson & Company, LLC, is a limited liability company, organized under the laws of the State of Delaware. Its citizenship is that of its sole member, Mead Johnson Nutrition Company. Defendants Mead Johnson Nutrition Company and Mead Johnson & Company, LLC, (together, “Mead”) are manufacturers of cow’s milk-based infant feeding products and market many of these products under the “Enfamil” brand name.

5. Defendant Abbott Laboratories (“Abbott”) is a corporation, incorporated under the laws of the State of Illinois. Its principal place of business is in Illinois. Abbott is a manufacturer of cow’s milk-based infant feeding products and markets many of its products under the “Similac” brand name.

6. Defendant The Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital is a non-profit corporation incorporated and registered to do business under the laws of the Commonwealth of Pennsylvania. Its principal place of business is Philadelphia, Pennsylvania. Pennsylvania Hospital is a registered name of The Pennsylvania Hospital of the University of Pennsylvania Health System. The sole member of The Pennsylvania Hospital of the University of Pennsylvania Health System is The Trustees of the University of Pennsylvania.

7. Defendant The Trustees of the University of Pennsylvania d/b/a Penn Medicine is a non-profit corporation registered to do business in the Commonwealth of Pennsylvania. Its principal place of business is Philadelphia, Pennsylvania. Penn Medicine is a registered name of The Trustees of the University of Pennsylvania.

III. JURISDICTION AND VENUE

8. This Court has jurisdiction in this matter pursuant to 42 Pa. C.S.A. § 931. Defendants

conduct authorized business in the Commonwealth of Pennsylvania. They have sufficient minimum contacts with and purposefully avail themselves of the markets of this Commonwealth. This suit arises out of Defendants' forum-related activities, such that the Court of Common Pleas of Philadelphia County's exercise of jurisdiction would be consistent with traditional notions of fair play and substantial justice.

9. Venue is proper in the Court of Common Pleas of Philadelphia County pursuant to Rules 1006(b), 1006(c)(1), and 2179(a) of the Pennsylvania Rules of Civil Procedure because Defendants are corporations or similar entities that regularly conduct business in Philadelphia County, which is also the county where Plaintiff's causes of action arose, and the county where the occurrences took place out of which Plaintiff's causes of action arose.

10. This action is not subject to the Compulsory Arbitration Program of the Court of Common Pleas of Philadelphia County because the amount in controversy, excluding interest and costs, is in excess of \$50,000.

IV. FACTUAL ALLEGATIONS

I.H.'s NEC Diagnosis

11. Infant plaintiff I.H. was born premature at Pennsylvania Hospital in Philadelphia, Pennsylvania on October 9, 2010.

12. At birth, I.H.'s gestational age was approximately 25 weeks and she weighed 879 grams.

13. Starting on October 9, 2010 until November 2, 2010, I.H. was fed mother's breast milk fortified with bovine-based Human Milk Fortifier (HMF), which upon information and belief was manufactured by Defendants Abbott and/or Mead.

14. Subsequently, between November 2, 2010 and November 19, 2010 I.H. was fed full formula feeds of Abbott's Special Care 20 cal/oz or Special Care 24 cal/oz bovine-based formula.

15. These feeds occurred despite the fact that Pennsylvania Hospital knew or should have known that cow's milk-based products increase the risk of NEC and that human milk can decrease the risk of NEC.

16. On November 20, 2010, Dr. Kelly Wade of the NICU diagnosed I.H. with stage II Medical NEC after noticing I.H.'s severely distended stomach and other symptoms consistent with NEC.

17. Between November 20 and November 23, Dr. Wade attempted to treat I.H.'s NEC using antibiotics without success, and on November 23 ordered for I.H. to be emergently transferred to St. Christopher's hospital for immediate surgical evaluation.

18. Upon arrival to the St. Christopher's NICU, I.H. was diagnosed with Stage IIIB Medical NEC, the most advanced and life-threatening stage of NEC, which indicates a perforation of the infant's intestinal track.

19. On Nov 23, 2010 I.H. underwent surgical intervention at St. Christopher's, undergoing an intestinal resection of the jejunum and distal ileum, removing part of her small intestines, as well as a primary anastomosis procedure to attach the two ends of the resected bowels together. At the end of the surgery, I.H. was placed on a wound VAC to assist in healing and blood clotting.

20. Subsequent, and secondary to the surgery and wound VAC placement, necrosis spread to I.H.'s left hand and forearm, and the NICU physicians amputated I.H.'s lower left extremity from the forearm down on December 8, 2010.

21. I.H. was in patient at the St. Christopher's NICU until her discharge home on February 15, 2011.

22. As a result of Defendants' actions described *infra*, I.H. suffered injuries, including but not limited to, a diagnosis of NEC, treatment with surgery and resection of a portion of her bowels, short gut syndrome secondary to NEC, intestinal and feeding difficulties, neurological injuries,

left lower extremity amputation at the forearm, and she continues to suffer developmental delays and feeding difficulties secondary to bowel resection and short gut syndrome.

***Cow's Milk-Based Feeding Products Are Known to Cause
NEC***

23. NEC is a devastating disease that is the most frequent and lethal gastrointestinal disorder affecting preterm infants. NEC develops when harmful bacteria breach the walls of the intestine, causing portions of the intestine to become inflamed and often to die. Once NEC develops, the condition can progress rapidly from mild feeding intolerance to systemic and fatal sepsis. Up to 30 percent of NEC-diagnosed infants die from the disease.

24. Preterm and low-birth-weight infants are especially susceptible to NEC because of their underdeveloped digestive systems. Extensive scientific research, including numerous randomized controlled trials, has confirmed that cow's milk-based feeding products cause NEC in preterm and low-birth-weight infants, which in turn may lead to other medical complications, surgeries, long-term health problems, and death.

Safer, Nutritionally Superior Alternatives to Cow's Milk-Based Products Exist

25. A range of options are available that allow preterm and low-birth-weight infants to be fed exclusively human milk-based nutrition. For example, in addition to the mother's own milk, an established network delivers pasteurized donor breast milk to hospitals nationwide. Moreover, hospitals have access to shelf-stable formula and fortifiers derived from pasteurized breast milk.

26. A diet based exclusively on breast milk and breast milk fortifiers provides all the nutrition necessary to support premature and low-birth-weight infants without the elevated risk of NEC associated with cow's milk-based products.

27. The Defendant Manufacturers' products not only pose a threat to infants' health, but also displace the human milk they could otherwise receive. This displacement only increases infants'

vulnerability to NEC.

28. Human milk-based nutrition nourishes infants while creating a significantly lower risk of NEC.

29. At the time the Injured Infant was fed the Defendant Manufacturers' products, the science clearly demonstrated to Defendants that these products cause NEC and greatly increase the likelihood that a baby will develop NEC, leading to severe injury and often death.

30. Despite the scientific evidence that the Defendant Manufacturers' cow's milk-based products present a dire threat to the health and development of preterm infants, the Defendant Manufacturers have made no changes to their products or the products' packaging, guidelines, instructions, or warnings. Instead, they have continued to sell their unreasonably dangerous products. In addition, they incentivize hospitals that know the risks to use their products by providing them to the hospital for free or at a significant discount, in order that vulnerable infants and their families will become accustomed to using their products before discharge. And, in fact, the Defendant Manufacturers offer contracts to hospitals—which the hospitals accept—that actually *prevent* the health care providers from offering alternative products—even safer ones—on pain of risking the hospital's advantageous formula pricing strategy.

31. Despite the scientific evidence that the Defendant Manufacturers' cow's milk-based products present a dire threat to the health and development of preterm infants and Pennsylvania Hospital knew or should have known of that threat, staff of Pennsylvania Hospital fed Similac and/or Enfamil cow's milk-based products after her birth instead of mother's human milk and/or donor human milk.

32. Despite the scientific evidence that the Defendant Manufacturers' cow's milk-based products present a dire threat to the health and development of preterm infants and Pennsylvania

Hospital knew or should have known of that threat, staff of Pennsylvania Hospital did not properly warn Ms. Wiger of those risks and alternatives to have avoided the cow's milk-based products.

Ms. Taylor Discovers Her Claim

33. Because of the Defendants' concealment and misrepresentations, described more fully herein, Ms. Taylor did not know, and had no reason to know or suspect, that I.H.'s NEC could have been caused by the Defendant Manufacturers' products.

***Despite Exercising Diligence, a Reasonable Investigation Did Not Reveal and
Would Not Have Revealed a Factual Basis Earlier
Because Defendants Hid the Cause of NEC from Ms. Taylor***

34. Despite exercising reasonable diligence, Ms. Taylor was unable to have made the discovery earlier via a reasonable investigation because the Defendants in this litigation concealed the wrongful cause of I.H.'s injuries.

35. Amidst the physical and emotional trauma of preterm childbirth, and having her child in the neonatal intensive care unit, shortly after learning of I.H.'s NEC diagnosis, Ms. Taylor undertook an investigation into the cause of the NEC by asking the doctors the cause of her NEC.

36. The health care providers at Penn Medicine responded only that I.H. had gotten NEC because she was born premature. Penn Medicine's response did not indicate that her NEC was caused by the Defendant Manufacturers' products.

37. Not one person at Penn Medicine mentioned that the Defendant Manufacturers' formula products could have caused I.H.'s injuries. Penn Medicine's response at the time did not give Ms. Taylor any reason to suspect any wrongdoing on the part of the Defendants.

38. Ms. Taylor is a layperson with no medical background or training that would have given her any reason to doubt the response she received from her Penn Medicine health care providers at the time.

39. Given that Penn Medicine’s health care providers were in charge of the care of her newborn infant, Ms. Taylor had no reason to doubt their word.

40. Additionally, the risk of necrotizing enterocolitis was not disclosed on the labeling or packaging of *any* of the Defendant Manufacturers’ products.

41. What is more, necrotizing enterocolitis is a disease that can occur in children who are *not* fed the Defendant Manufacturers’ products, and the Defendant Manufacturers have worked to mislead parents into a false sense of security about the use of those products. Publicly disseminated materials from each Defendant Manufacturer disguise the role their products play in causing the disease—and affirmatively say, even today, that their products are safe and do not cause NEC. In fact, some publicly disseminated materials from the formula manufacturers even suggest that formula may help *reduce* the risk of this terrible and potentially fatal disease.

42. For example, Abbott’s website stays that “[t]he specific cause of NEC is unknown, but it’s most often seen in very low birth weight premature babies,” and that “about 10% of babies who are born prematurely develop NEC.” The website suggests that “new preliminary studies” suggest for the first time that “NEC prevention may . . . be possible” with the use of human milk oligosaccharides to “dramatically curb intestinal inflammation” and reduce the risk of NEC. Abbott states that these human milk oligosaccharides are found in “certain Similac formulas” although they are “not currently available in Similac’s premature infant formulas.”¹ Likewise, the website for Mead Johnson’s products states that necrotizing enterocolitis is “one of the most common and serious intestinal disease[s] among premature babies.” And it deflects responsibility

¹ The Role of HMOs in Reducing NEC, <https://www.nutritionnews.abbott/pregnancy-childhood/prenatal-breastfeeding/the-promising-role-of-hmos-in-reducing-risk-of-nec/> (last visited July 28, 2023).

from Mead Johnson’s products: “Necrotizing enterocolitis happens when tissue in the small or large intestine is injured or inflamed.”²

43. Because of the misleading information distributed by the Defendant Manufacturers, as further detailed *infra*, any research conducted by Ms. Taylor immediately after I.H.’s diagnosis, or at any time prior to seeing an advertisement, would not have led a reasonable person to suspect that the Defendant Manufacturers’ products could have caused I.H.’s injuries.

44. Ms. Taylor also did not know, and had no reason to know or suspect, that Penn Medicine breached its duty of care by distributing the Defendant Manufacturers’ products to her. Not only was Ms. Taylor unaware that the Defendant Manufacturers’ products caused I.H.’s injuries, but the Defendant Manufacturers’ distribution agreements with Penn Medicine—which allowed Penn Medicine to secure sweetheart deals for otherwise expensive premature infant formula in exchange for product placement and access to the hospital staff—were also not public or knowable to Ms. Taylor, nor could any reasonable investigation outside of litigation have uncovered the terms of those agreements.

Despite Exercising Reasonable Diligence, the Defendants’ Fraudulently Concealed the Risks of NEC from Defendant Manufacturers’ Products to Divert, Prevent, and Mislead Plaintiff Regarding the Cause of Her Child’s NEC Diagnosis

45. In addition to the averments above, the Defendants have acted in concert to fraudulently convey false and misleading information concerning the risk of NEC, and potentially death, caused by Defendant Manufacturers’ preterm infant formula products.

46. The Defendants’ actions as set forth herein constitute knowing misrepresentation, omission, suppression, and concealment of material facts, made with the intent that Plaintiff would

² Special Feeding Concerns for Preemies, <https://www.enfamil.com/articles/special-feeding-concerns-for-preemies/> (last visited July 29, 2023).

rely upon such concealment, suppression, or omission, in connection with the use of Defendants' preterm infant products.

47. Plaintiff did not know, and could not learn, the truth concerning the uses, risks and benefits of Defendant Manufacturers' preterm infant products due to Defendants' deliberate misrepresentations and concealment, suppression and omission of material facts and important information regarding the risks of NEC, and potentially death, from the products.

48. Moreover, Defendant Hospital further participated in the intentional concealment—on information and belief, it allowed the Defendant Manufacturers' sales representatives into its hospital to provide samples and free products that did not warn of their serious dangers, and to provide “education” to its NICU staff that was incomplete as to the true risks of feeding their patients the Defendant Manufacturers' products.

49. Based upon information and belief, during the relevant time period, Pennsylvania Hospital, Penn Medicine, and the Hospital of the University of Pennsylvania stocked formula products from both Abbott and Mead.

50. Additionally, Defendant Hospital failed to inform Ms. Taylor that the Defendant Manufacturers' products caused Plaintiff's NEC, even when she directly asked the cause. As noted above, after learning of Plaintiff's NEC diagnosis, Ms. Taylor was understandably concerned about the degrading health of her newborn infant. As any concerned parent would do, Ms. Taylor asked Plaintiff's health care providers at Defendant Hospital why a premature infant like I.H. was suddenly diagnosed with a terrible disease like necrotizing enterocolitis; that is, she asked Defendant Hospital what caused Plaintiff's injury. But even though Defendant Hospital knew of the increased risk of NEC from formula, it did not disclose that the formula provided to I.H. could increase the risk of NEC to preterm infants, responding only that I.H. had gotten NEC solely

because she was born premature. Not one person at the NICU mentioned that the Defendant Manufacturers' formula products could have been the cause of Plaintiff's injuries.

51. Defendant Hospital was aware that the Defendant Manufacturers' products caused NEC in premature infants. Defendant Hospital was also aware that the Defendant Manufacturers did not provide warnings on their products. However, Defendant Hospital did not warn Ms. Taylor of the risks of the products. Instead, and notwithstanding the sweetheart deal Defendant Hospital agreed to in exchange for preterm infant formula at little to no cost, Defendant Hospital repeatedly informed Ms. Taylor that it would do everything it could possibly do to keep her infant safe. Though this was clearly not true given the known risks of preterm formula for babies like I.H., it was enough for Ms. Taylor to trust that Defendant Hospital was providing preterm formula in the best interest of her child.

52. Defendants' affirmative acts of fraud and concealment, as averred herein, diverted, prevented, and/or mislead Plaintiff from discovering the medical cause of her child's NEC diagnosis.

The Defendant Manufacturers' False and Misleading Marketing Regarding Cow's Milk-Based Infant Products

53. Abbott and Mead have aggressively marketed their cow's milk-based products as medically endorsed and nutritionally equivalent alternatives to breast milk, including prior to the Injured Infant's birth.

54. Abbott's and Mead's marketing approach includes targeting the parents of preterm infants while they are still in the hospital with messages that the Defendant Manufacturers' cow's milk formulas and fortifiers are necessary for the growth and development of their vulnerable children. Often these tactics implicitly discourage mothers from breastfeeding, which reduces the mother's supply of breast milk. None of the Defendant Manufacturers' marketing materials, including their

promotional websites, reference the science showing how significantly their products increase the risk of NEC.

55. For example, upon information and belief, Mead creates information booklets for parents of premature infants to help answer some of their questions and concerns about having a premature infant in the NICU that it provides to hospitals for dissemination to parents. While Mead's booklets explain feeding options for premature infants, including formula, they do not mention that Mead's premature formula and fortifier products increase the risk of premature infants developing necrotizing enterocolitis. Instead, the booklets advise parents that sometimes a combination of breast milk and formula may be best and that premature infants will be happy and healthy or nourished and healthy regardless of whether they are receiving breast milk or formula.

56. Similarly, upon information and belief, Abbott publishes a pediatric nutrition product guide that is available online for anyone, including parents, to access wherein Abbott advises that "human milk alone does not meet all the nutritional needs of preterm infants" and that the formulations of its products, which are based on decades of research and scientific publications, are "specially designed to meet the nutritional requirements of preterm infants and can be fed with confidence to most of the preterm infants in the NICU." Nowhere in its product guide does Abbott reference that its products increase the risk of necrotizing enterocolitis.

57. Abbott also has a consumer-facing website accessible to anyone online, including parents, that specifically discusses nutrition for premature infants, wherein Abbott tells parents of premature infants that "your baby's nutrient needs are greater than what breast milk alone can provide" and that a "human milk fortifier" may be added to breastmilk to "add[] proteins, vitamins, and minerals to help support a preemie's high nutrition needs for growth and development." Nowhere in its discussion of preterm infant fortifiers or formulas does Abbott state that its products

increase the risk of necrotizing enterocolitis or that they pose more of a risk that just providing preterm infants with breast milk only. Nor does Abbott disclose that the “human milk fortifier” is actually a cow’s milk based product and not a human milk-based product, which misleads consumers.

58. Upon information and belief, both Mead and Abbott also provide materials and programs to the hospitals and the physicians and medical staff who are treating premature infants about the manufacturers’ preterm products. Upon information and belief, these materials represent that the manufacturers’ preterm products are safe and necessary for preterm infants. Mead and Abbott rely on the physicians and medical staff to not only use their products in the NICU, but to convey these messages to the parents of premature infants in their care.

59. Undoubtedly aware of the impact of their advertising, the Defendant Manufacturers, along with other formula manufacturers, are willing to spend massive sums to disseminate their message.

60. Recognizing the abuse and dangers of infant formula marketing, in 1981, the World Health Assembly—the decision-making body of the World Health Organization—developed the International Code of Marketing of Breast-milk Substitutes (“the Code”), which required companies to acknowledge the superiority of breast milk, the negative effect on breastfeeding of introducing partial bottle-feeding, and the difficulty of reversing the decision not to breastfeed. The Code also forbade advertising or other forms of promotion of formula to the general public, as well as providing sample products to mothers or members of their families.

61. While Abbott and Mead acknowledge the Code on their websites and claim to support the effort to encourage mothers to breastfeed for as long as possible, this is little more than lip service. Instead, the Defendant Manufacturers’ aggressive marketing exploits new parents’ darkest fears—

that the nutrition they are supplying to their child will not provide the best chance of survival—while wholly failing to warn that their products come with a significantly increased risk of NEC.

62. For example, Abbott’s website, on a page titled “Infant Formula Marketing,” states: “We agree with the World Health Organization that breastfeeding provides the best nutrition for babies, and we support its goal to increase breastfeeding. We also recognize that for infants who aren’t breastfed—for medical reasons or otherwise—infant formula is the only appropriate, safe alternative to meet babies’ nutritional needs.” This statement ignores the existence of donor milk, as well as human milk-based formula.

63. Abbott markets and sells multiple products specifically targeting preterm and low-birthweight infants, including Liquid Protein Fortifier, Similac NeoSure, Similac Human Milk Fortifiers, Similac Special Care 20, Similac Special Care 24, Similac Special Care 24 High Protein, and Similac Special Care 30. In advertising these products, Abbott emphasizes the products’ purported ability to assist underdeveloped babies in reaching their growth targets. For example, on the since-edited webpage regarding Similac NeoSure, Abbott noted: “Your premature baby didn’t get her full 9 months in the womb, so her body is working hard to catch up. During her first full year, feed her Similac NeoSure, a nutrient-enriched formula for babies who were born prematurely, and help support her development.” Yet, no mention was made of the accompanying significantly increased risk of NEC. At some point, the website was edited to remove this statement. However, upon information and belief, the statement remained on the website until at least December 2020.

64. Abbott’s website also contains product information and a downloadable guide for each of its products specifically targeting preterm and low-birth-weight infants, including Liquid Protein Fortifier, Similac NeoSure, Similac Human Milk Fortifiers, Similac Special Care 20, Similac

Special Care 24, Similac Special Care 24 High Protein, and Similac Special Care 30. None of these pages or guides contain any mention of NEC or that the products specifically increase the risk of NEC. Indeed, a search of Abbott’s website for “necrotizing enterocolitis” returns no hits. Instead, Abbott states that “enteral feeding” – which includes breast milk and donor milk – have been “associated with” things like “[s]pitting up, abdominal distension” or “other signs of intestinal dysfunction.” This statement is entirely misleading, as it improperly indicates that the risk of things like “spitting up” are the same for premature infants using Abbott’s products and premature infants receiving breast milk or donor milk, equates formula to non-cow’s milk-based feeding options like breast milk and donor milk, fails to mention NEC, and minimizes the risk of its products.

65. Mead markets and sells multiple products specifically targeting premature infants, including Enfamil NeuroPro EnfaCare Infant Formula, Enfamil Premature Infant Formula 24 Cal High Protein, Enfamil Premature Infant Formula 30 Cal with Iron, Enfamil Premature Infant Formula 24 Cal with Iron, Enfamil Premature Infant Formula 20 Cal with Iron, Enfamil 24 Cal Infant Formula, and Enfamil Human Milk Fortifier (acidified liquid and powder). In advertising these products, Mead emphasizes the purported similarities between its formula and breast milk, while failing to include any information about the nutritional deficits and dangers that accompany formula use. For example, the since-edited webpage for Enfamil Enfacare stated: “Premature babies fed Enfamil® formulas during the first year have achieved catch-up growth similar to that of full term, breastfed infants” and noted that Enfamil formulas include “expert-recommended levels of DHA and ARA (important fatty acids found naturally in breast milk) to support brain and eye development.”

66. One Enfamil advertisement, introducing a new product line called Enfamil NeuroPro, is entirely focused on favorably comparing Enfamil's formula to breast milk, without any mention of the product's extreme risks. Indeed, the terms "human milk" and "breast milk" are used 13 times in the advertisement, including in such statements as "for decades human milk has inspired the advancements in Enfamil formulas and now through extensive global research, we are taking an even closer look at human milk" and "only Enfamil NeuroPro has a fat blend of MFGM and DHA previously found only in breast milk." The webpage for the product has made similar manipulative claims, stating "Enfamil is backed by decades of breast milk research and multiple clinical studies" and it claims that "to create our best formulas, we collaborated on some of the most extensive breast milk studies to date[.]"

67. Mead's website also contains product information for each of its products specifically targeting preterm and low-birth-weight infants, including Enfamil NeuroPro EnfaCare Infant Formula, Enfamil Premature Infant Formula 24 Cal High Protein, Enfamil Premature Infant Formula 30 Cal with Iron, Enfamil Premature Infant Formula 24 Cal with Iron, Enfamil Premature Infant Formula 20 Cal with Iron, Enfamil 24 Cal Infant Formula, and Enfamil Human Milk Fortifier (acidified liquid and powder). None of these pages contain any mention of NEC or that the products specifically increase the risk of NEC. Indeed, a search of Mead's website for "necrotizing enterocolitis" returns no hits. Instead, Mead advertises on its website that it "has led the way in developing safe, high-quality, innovative products" – including preterm products – "to help meet the nutritional needs of infants."

68. Formula manufacturers have long used their relationships with hospitals and the discharge process to encourage parents to substitute formula for breast milk. They offer free or reduced-cost formula to hospitals for use with infants before discharge. And they offer free formula, coupons,

and even entire gift baskets to parents before their infants' discharge from the NICU or hospital.

69. Through this early targeting, the Defendant Manufacturers create brand loyalty under the guise of a “medical blessing,” in hopes that new parents continue to use formula after they leave the hospital, resulting in increased expense for parents, significantly increased risk for babies, and increased profit for the Defendant Manufacturers. The Defendant Manufacturers' giveaways and gift baskets send confusing signals to mothers who are simultaneously being encouraged to breastfeed by their healthcare professionals, and they have been shown to negatively impact breastfeeding rates.

70. Further, when the Defendant Manufacturers recognized a shift in the medical community towards an exclusive breast milk-based diet for premature infants, Abbott developed a product called “Similac Human Milk Fortifier,” and Mead developed “Enfamil Human Milk Fortifier.” These names are misleading in that they suggest that the products are derived from breast milk, when, in fact, they are cow's milk-based products. The packaging appears as:



71. The Defendant Manufacturers have designed powerful misleading marketing campaigns to deceive parents into believing that: (1) cow's milk-based products are safe, including for preterm

infants; (2) cow's milk-based products are equal, or even superior, substitutes to breast milk; (3) cow's milk-based products are necessary for proper growth and development of preterm infants; and (4) physicians consider the Defendant Manufacturers' cow's milk-based products to be a first choice. This marketing scheme is employed despite all Defendants knowing of and failing to warn of the extreme risk of NEC and death that cow's milk-based products pose to preterm infants like the Injured Infant.

72. The Defendant Manufacturers have also designed powerful marketing campaigns to both the general public and health care providers at hospitals like Pennsylvania Hospital. The Defendant Manufacturers know that sales made to hospitals are key drivers of brand loyalty, and thus are a key opportunity to drive better downstream business—*i.e.*, retail purchases by parents after they have left the hospital. On information and belief, the Defendant Manufacturers know that the formula products used in a hospital's NICU are related to getting and keeping the overall hospital contracts. And the Defendant Manufacturers know that, just like any celebrity endorsement, when mothers of newborn infants see medical professionals using a certain brand, the mothers are more likely to continue to purchase that same brand after discharge. The Defendant Manufacturers are thus heavily motivated to ensure that NICU departments are using their products.

73. Abbott and Mead Johnson focus their sales teams and training heavily on hospital NICU departments. They train their sales representatives how to increase the number of babies on their formula, and they emphasize the need to be the dominant formula manufacturer in the NICU so they can own that profitable ground and secure a great return on their substantial investment in NICU formula and other products.

74. To leverage hospitals' NICUs and secure babies in the hospital and at retail, the Manufacturer Defendants pull out all the stops to convince hospitals, including Defendant Hospital, to purchase their products. For example: Abbott and Mead Johnson provide samples of their products to hospitals for free.

75. On information and belief, to get the hospitals on board with supplying their formula for premature infants, Abbott and Mead Johnson work with hospitals to secure contracts that have special pricing discounts if a certain level of the formula-fed babies in the hospital receive just that one manufacturer's products; similar to a restaurant being a Coke or Pepsi restaurant. And notwithstanding the increased risk of the Defendant Manufacturers' products for the hospitals' most fragile patients—the preterm infants—the decision makers at these hospitals seek out these types of contracts to better the hospitals' own bottom lines.

76. On information and belief, Abbott and Mead Johnson also seek promises and/or assurances that the full range of health care providers at the hospitals, including the nurse practitioners and other staff who would pull the infant formula off the shelf, are grabbing the respective company's own formula products to give to the preterm infants. The goal of this tactic was to ensure that the Defendant Manufacturers and key people at the hospital would be sending a shared message that the preterm infant formula products were safe and without risk, even though that is not what the science said.

77. On information and belief, Abbott and Mead Johnson also seek promises and/or assurances that the full range of health care providers at the hospitals, including the nurse practitioners and other staff who would pull the infant formula off the shelf, are grabbing the respective companies' own formula products to give to the preterm infants. The goal of this tactic was to ensure that the Defendant Manufacturers and key people at the hospital would be sending a shared message that

the preterm infant formula products were safe and without risk, even though that is not what the science said.

78. On information and belief, prior to I.H.'s birth, Abbott sent sales representatives to Defendant Hospital. Those sales representatives provided information about Abbott's products to Defendant Hospital's staff via conversations, presentations, and written pamphlets. This information indicated that Abbott's products were safe to give to preterm infants like I.H. Abbott maintains call logs that detail which sales representatives visited the hospitals, which days they visited, and which products they discussed. These sales representatives did not disclose that Abbott's products could cause NEC in preterm infants.

79. On information and belief, prior to I.H.'s birth, Mead Johnson sent sales representatives to Defendant Hospital. Those sales representatives provided information about Mead Johnson's products to Defendant Hospital's staff via conversations, presentations, and written pamphlets. This information indicated that Mead Johnson's products were safe to give to preterm infants like I.H. Mead Johnson maintains call logs that detail which sales representatives visited the hospitals, which days they visited, and which products they discussed. These sales representatives did not disclose that Mead Johnson's products could cause NEC in preterm infants.

80. Mead Johnson and Abbott believed and intended that the misrepresentations that its sales representatives shared with Defendant Hospital would be used to make feeding decisions for preterm infants like I.H.

The Defendant Manufacturers' Inadequate Warnings

81. Although Mead promotes an aggressive marketing campaign designed to convince parents that its cow's milk-based products are safe and necessary for the growth of a premature infant, the product is in fact extremely dangerous for premature infants. Enfamil products significantly increase the chances of a premature infant developing potentially fatal NEC.

82. The Enfamil products Mead markets specifically for premature infants are commercially available at retail locations and online. No prescription is necessary.

83. Despite knowing of the risk of NEC, the packaging of Mead's products does not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with Mead's products, or of the magnitude of this increased risk. Mead likewise did not provide instructions or guidance for how to avoid NEC.

84. Mead cites no medical literature or research to guide the use of its products.

85. Despite knowing of the risk of NEC, Mead did not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with its products, or of the magnitude of this increased risk. Mead likewise did not provide instructions or guidance for how to avoid NEC.

86. Mead deceived the public, parents, physicians, other medical professionals, and medical staff into believing that Enfamil products were a safe and necessary alternative, supplement and/or substitute to breast milk.

87. Mead Johnson failed to provide, and continues to fail to provide, a full accounting of the risk of NEC as documented, by underrepresenting and misrepresenting the risk to the public and the medical community.

88. Despite knowing that its products were being fed to premature infants, often without the parents' informed consent, Mead failed to require or recommend that medical professionals inform parents of the significant risk of NEC or to require that parental consent be obtained prior to the products being fed to their babies. Like Mead, Abbott promotes an aggressive marketing campaign designed to make parents believe that its products are safe and necessary for the growth of premature infants, despite the products in fact being extremely dangerous for premature infants.

Abbott's products significantly increase the chances of a premature infant getting potentially fatal NEC.

89. The products Abbott markets specifically for premature infants are available at retail locations and online. No prescription is necessary.

90. Despite knowing of the risk of NEC, Abbott did not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with its products, or of the magnitude of this increased risk. Abbott likewise did not provide instructions or guidance for how to avoid NEC.

91. Abbott deceived the public, parents, physicians, other medical professionals, and medical staff into believing that its products were a safe and necessary alternative, supplement and/or substitute to breast milk.

92. Despite knowing of studies documenting an increased risk of NEC from its products, Abbott did not act to make parents or the medical community aware of those risks, and instead took steps to conceal or prevent those risks from becoming public. Despite knowing that its products were being fed to premature infants, often without the parents' informed consent, Abbott failed to require or recommend that medical professionals inform parents of the significant risk of NEC or to require that parental consent be obtained prior to the products being fed to their babies.

Penn Medicine's Failure to Warn

93. On information and belief, Penn Medicine, which operates Pennsylvania Hospital, was aware of the significantly increased risk of NEC and death associated with providing Abbott's and Mead's cow's milk-based products to its premature infant patients. It knew or should have known that feeding these cow's milk-based products can cause NEC in premature infants who otherwise would not have developed this devastating condition. It also knew or should have known that

human milk decreases the risk of NEC for premature infants. However, instead of warning of the dangers, or supplying human milk-based feeding products to preterm infants like the Injured Infant, Penn Medicine has continued to source, distribute, and supply the Defendant Manufacturers' products in its hospitals without any adequate warning. Further, the Defendant Hospital created a study putting infants, such as I.H. at great risk by providing them with bovine based formula instead of exclusive human milk-based products.

94. To that end, Penn Medicine has participated in studies designed to increase the use of donor milk while, at the same time, reducing formula feeding in neonates. The University of Pennsylvania School of Nursing, an affiliate of Penn Medicine, has conducted extensive research into the risks associated with feeding formula to premature infants. It recently partnered with the National Institute of Nursing Research to publish clinical determinations based on its experience “changing hospital systems and influencing policy,” and its findings were unequivocal:

This is what we know about the science of human milk: it reduces the risk of necrotizing enterocolitis, reduces the risk of infection, [and] creates greater enteral feed tolerance and more rapid weaning from intravenous nutrition. . . .

95. Other Penn Medicine research has similarly concluded that “[h]uman milk decreases the incidence and severity of . . . necrotizing enterocolitis (NEC).”

96. Given it was known that human milk decreases the incidence and severity of NEC, it was also known or should have been known that cows milk-based formula increases the incidence and severity of NEC.

97. Penn Medicine also purports to adhere to the tenets of the “Baby Friendly Hospital Initiative,” which seeks to increase rates of breastfeeding initiation, exclusivity, and diet duration. The “Baby Friendly Hospital Initiative” specifically targets a reduction in the rates of NEC in preterm infants by encouraging implementation of exclusive breast milk diets among new mothers. Although Pennsylvania Hospital has maintained its “Baby Friendly” designation for years, it has

not eliminated or restricted the use of formula or fortifier for preterm infants in its hospitals.

98. Given it was known since at least the early 2000s, and as far back as the 1990s, that human milk decreases the incidence and severity of NEC, it was also known or should have been known that cows milk-based formula increases the incidence and severity of NEC.

99. Penn Medicine also purports to adhere to the tenets of the “Baby Friendly Hospital Initiative,” which seeks to increase rates of breastfeeding initiation, exclusivity, and diet duration. The “Baby Friendly Hospital Initiative” specifically targets a reduction in the rates of NEC in preterm infants by encouraging implementation of exclusive breast milk diets among new mothers. Although Pennsylvania Hospital has maintained its “Baby Friendly” designation for years, it has not eliminated or restricted the use of formula or fortifier for preterm infants in its hospitals.

100. Finally, medical providers and staff at Penn Medicine have acknowledged the risks associated with providing the Defendant Manufacturers’ cow’s milk-based products to premature infant patients instead of breast milk-based nutrition. In an internal newsletter from 2012 touting donor milk programs, Penn Medicine acknowledged the benefits of a human milk-based diet, quoting a staff lactation consultant:

Donor milk is not inexpensive. It costs about \$4.25 per ounce, but the return on investment is huge. “Preemies given mother’s milk get discharged three to four days sooner and also have a six to 10 times lower risk of getting a gastrointestinal complication called necrotizing enterocolitis,” Carpenter said, adding that the infection can cost up to \$250,000 to treat. The average cost to provide a preemie with donor milk: \$125.

101. These statements demonstrate that Penn Medicine knew or should have known of the high increased risk of NEC for premature infants posed by the Defendant Manufacturers’ products.

102. Although Penn Medicine knew or should have known of the serious danger of the Defendant Manufacturers’ products, it has continued to purchase, supply, and distribute these

products to preterm infants without providing full and adequate warnings of the attendant risks to parents, healthcare professionals, and other medical staff at its relevant facilities. As a result, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products at Pennsylvania Hospital, causing their injuries. This occurred even though hospitals across the country, including Pennsylvania Hospital, warn and obtain consent from parents before providing other safer forms of nutrition, such as donor breast milk.

103. Penn Medicine's failure to warn of the risks posed by the Defendant Manufacturers' products is entrenched (and compounded) by the financial benefits it accrues from its relationships with the Defendant Manufacturers. On information and belief, it has received the Defendant Manufacturers' cow's milk-based products for free and/or at a significant discount, and has granted their sales representatives access to its healthcare professionals and medical staff. These sales representatives have provided deceptive information that Penn Medicine reasonably knew or should have known would ultimately reach parents through those staff. This arrangement dovetails with the Defendant Manufacturers' own marketing strategies" and use of salespersons.

Safer Alternative Designs

104. The Defendant Manufacturers' cow's milk-based products made specifically for premature infants are unreasonably unsafe for those infants. The Defendant Manufacturers could have used pasteurized breast milk instead of cow's milk in their products, which would have produced a safer product.

105. Prolacta Bioscience manufactures and sells breast milk-based feeding products, specifically designed for preterm infants, which contain no cow's milk. This alternative design provides all the necessary nutrition for growth and development that cow's milk-based products provide, without the same unreasonably dangerous and deadly effects.

106. On information and belief, Abbott and Mead were aware of the significantly increased risk of NEC and death associated with their cow's milk-based products, and instead of warning of the dangers, or removing them altogether, Abbott and Mead have continued to use cow's milk as the foundation of their products.

CAUSES OF ACTION
COUNT I: STRICT LIABILITY FOR DESIGN DEFECT
(Against Abbott and Mead)

107. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

108. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to manufacture, sell, and distribute their products in a manner that was not unreasonably dangerous.

109. Abbott and Mead also owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to manufacture, sell, and distribute their products in a manner that was merchantable and reasonably suited for their intended use.

110. Abbott and Mead knew that their products would be used to feed premature infants like the Injured Infant and knew (or reasonably should have known) that use of their cow's milk-based products significantly increased the risk of NEC, serious injury, and death, and that such use was therefore unreasonably dangerous to premature infants, not reasonably suited for the use intended, not merchantable, and had risks that exceeded a reasonable buyer's expectations. Nonetheless, they continued to sell and market their defective products as appropriate for premature infants.

111. The Injured Infant ingested Abbott and/or Mead's unreasonably dangerous cow's milk-based products. The risks of feeding those products to the Injured Infant outweighed the benefits. An ordinary consumer would not expect those products to carry a significant risk of serious injury

and death from NEC.

112. Abbott and Mead knew (or reasonably should have known) that breast milk-based nutrition did not carry the same risks of NEC, serious injury, and death that their products do.

113. Abbott's and Mead's products contained cow's milk at the time they left the manufacturing facility.

114. Abbott and Mead did not develop a human-milk based product that was safer for premature infants and did not reformulate their products to reduce the risk of NEC, serious injury, and death, even though doing so was economically and technologically feasible and even though pasteurized breast milk was an available alternative.

115. Abbott's and/or Mead's products were fed to the Injured Infant, which caused and/or increased the risk of their NEC and injuries.

116. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost

revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;

- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT II: STRICT LIABILITY FOR FAILURE TO WARN
(Against Abbott and Mead)**

117. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

118. Abbott and Mead, as the manufacturers and/or sellers of the infant products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide adequate warnings or instructions about the dangers and risks associated with the use of their products with preterm infants, specifically including but not limited to the risk of NEC, serious injury, and death.

119. Abbott's and Mead's duty to warn is part of their general duty to design, manufacture, and sell their infant products in a manner that is reasonably safe for their foreseeable uses. By designing their products with cow's milk-based ingredients, Abbott and Mead undertook a duty to warn of the unreasonable risk of harm posed by those ingredients, specifically including the significantly increased risk of NEC, severe injury, and death. The failure to warn makes the

products at issue in this litigation unreasonably dangerous.

120. Specifically, Abbott and Mead breached their duty to warn of the foreseeable risks of the infant products at issue in this litigation because they knew or should have known that their cow's milk-based premature infant products would be fed to premature infants like the Injured Infant, and that their products might cause the Injured Infant to develop NEC, severe injury, or death, yet they failed to provide adequate warnings of those risks. Among other risks, the Defendant Manufacturers:

- a. Failed to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death for the Injured Infant; and/or
- b. Failed to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or
- c. Inserted warnings and instructions on their products that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC and death; and/or
- d. "Black box"-type warning that their cow's milk-based products are known to significantly increase the risk of NEC and death when compared to breast milk in premature infant; and/or
- e. Failed to disclose well-researched and well-established studies that linked cow's milk-based products to NEC and death in premature infants; and/or
- f. Failed to insert a warning or instruction to healthcare professionals and other medical staff in the hospital that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed the

Defendant Manufacturers' products, notwithstanding their substantial risks; and/or

- g. Failed to provide a warning in a method reasonably calculated or expected to reach the parents of newborns, like the Plaintiff Parent; and/or
- h. Failed to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products.

121. Abbott's and Mead's products contained cow's milk at the time they left the manufacturing facility.

122. As a direct and proximate result of the inadequacy of the warnings and the pervasive marketing campaigns suggesting the safety and necessity of the Defendant Manufacturers' products, the Injured Infant were fed cow's milk-based products, which caused and/or increased risk of their developing NEC.

123. The unwarned-of risks are not of a kind that an ordinary consumer would expect. Had physicians and medical staff known of the extreme risk associated with feeding premature infants cow's milk-based formula, they would not have fed the Injured Infant those products. Had the Plaintiff Parent known of the significant risks of feeding the Injured Infant cow's milk-based formula, they would not have allowed such products to be fed to the Injured Infant.

124. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;

- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendants Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT III: NEGLIGENCE
(Against Abbott and Mead)**

125. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

126. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to exercise reasonable care to design, test, manufacture, inspect, and distribute a product free of unreasonable risk of harm to users, when such products are used in their intended manner and for their intended purpose.

127. At all times relevant to this action, the Injured Infant's healthcare professionals and medical staff used the products at issue in their intended manner and for their intended purpose.

128. Abbott and Mead, directly or indirectly, negligently, and/or defectively made, created, manufactured, designed, assembled, tested, marketed, sold, and/or distributed the cow's milk-based infant products at issue in this litigation and thereby breached their duty to the general public and the Plaintiff Parent.

129. Specifically, although Abbott and Mead knew or reasonably should have known at the time of production that their cow's milk-based infant products significantly increased the risk of NEC, serious injury, and death, they failed to act in a reasonably prudent manner and breached their duty by:

- a. Failing to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death for the Injured Infant; and/or
- b. Failing to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or
- c. Inserting warnings and instructions that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC and death; and/or
- d. Failing to insert a large and prominent "black box"-type warning that their cow's milk-based products are known to significantly increase the risk of NEC and death when compared to breast milk in premature infants; and/or
- e. Failing to provide well-researched and well-established studies that linked cow's milk-based products to NEC and death in premature infants; and/or
- f. Failing to insert a warning or instruction to healthcare professionals and other medical staff in the hospital that parents should be provided information necessary

- to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risks; and/or
- g. Failing to provide a warning in a method reasonably calculated/expected to reach the parents of newborns, like the Plaintiff Parent; and/or
- h. Failing to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products.

130. In addition, although Abbott and Mead knew or reasonably should have known at the time of production that their cow's milk-based products significantly increased the risk of NEC, serious injury, and death, they failed to act in a reasonably prudent manner and breached their duty by failing to perform the necessary process of data collection, detection, assessment, monitoring, prevention, and reporting or disclosure of adverse outcomes in infants who ingest their products.

131. As a direct and proximate result of the Defendant Manufacturers' failure to act in a reasonably prudent manner and their breach of duty, the Injured Infant was fed cow's milk-based products, which caused and/or increased the risk of their developing NEC.

132. Had Abbott and Mead satisfied their duties to the consuming public in general, the Injured Infant would not have been exposed to their unreasonably dangerous cow's milk-based products.

133. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of

life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;

- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendants Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT IV: INTENTIONAL MISREPRESENTATION
(Against Abbott and Mead)**

134. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

135. At all times relevant to this action, the Injured Infant consumed the Defendant Manufacturers' products in their intended manner and for their intended purpose.

136. Abbott and Mead, as the manufacturers and/or sellers of the infant products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide truthful, accurate, fulsome information about the risks and benefits of using their products when used in the intended manner and for the intended purpose.

137. Abbott and Mead breached their duty through misrepresentations made to consumers in their advertising and promotional materials, as described in previous paragraphs and incorporated

herein, each of whom were foreseeable and intended recipients of this information.

138. Specifically, upon information and belief, Abbott and Mead made the following false statements of material fact on an ongoing and repeated basis to the public, including patient consumers and parents like Plaintiff Parent and prior to the time the Injured Infant was fed their products:

- a. That their cow's milk-based products were safe and beneficial for premature infants when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or
- b. That their cow's milk-based products were necessary to the growth and nutrition of premature infants, when they knew or should have known that their products were not necessary to achieve adequate growth; and/or
- c. That their products have no serious side effects, when they knew or should have known the contrary to be true; and/or
- d. That cow's milk-based products were safe for premature infants; and/or
- e. That cow's milk-based products were necessary for optimum growth; and/or
- f. That cow's milk-based products were similar or equivalent to breast milk; and/or
- g. That their products were safe and more like breast milk than other infant products and that they had removed the harmful ingredients of cow's milk when, in fact, the cow's milk in their products was still capable of causing NEC, serious injury, and death; and/or
- h. That their products were safe for and provided better nutrition and growth to premature infants than donor milk, a non-cow's milk-based alternative to breast milk; and/or

- i. That their products can fed with confidence to most of the preterm infants in the NICU and/or that premature infants would be happy and health or nourished and health on their products; and/or
- j. That their products were based on up-to-date science, which made them safe for premature infants; and/or
- k. Omitting the material fact that their products significantly increased the risk of NEC in premature infants, including omitting this material fact from their publicly available product information, marketing materials, and websites.

139. Abbott and Mead had actual knowledge, or, at a minimum, a reckless indifference, to whether the aforementioned misrepresentations were false.

140. In addition to the above, Abbott and Mead, upon information and belief, also made the following false statements of material fact to Plaintiff Parent:

- a. Omitting from coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent that their products significantly increased the risk of NEC in premature infants; and/or
- b. Omitting from the packaging and labeling of their products provided to Injured Infant that their products significantly increased the risk of NEC in premature infants; and/or
- c. Representing that their cow's milk-based products were safe and beneficial for premature infants on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or

- d. Representing that their cow's milk-based products were safe and beneficial for premature infants on the packaging and labeling of their products provided to Injured Infant when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or
- e. Representing that their cow's milk-based products were necessary to the growth and nutrition of premature infants on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent when they knew or should have known that their products were not necessary to achieve adequate growth; and/or
- f. Representing that their cow's milk-based products were necessary to the growth and nutrition of premature infants on the packaging and labeling of their products provided to Injured Infant when they knew or should have known that their products were not necessary to achieve adequate growth; and/or
- g. Representing that their cow's milk-based products were similar or equivalent to breast milk on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent; and/or
- h. Representing that their cow's milk-based products were similar or equivalent to breast milk on the packaging and labeling of their products provided to Injured Infant; and/or
- i. Representing that their cow's milk-based products could be fed with confidence to premature infants and/or that premature infants would be healthy regardless of whether they were fed their cow's milk-based products or breast milk on coupons,

gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent; and/or

- j. Representing that their cow's milk-based products could be fed with confidence to premature infants and/or that premature infants would be healthy regardless of whether they were fed their cow's milk-based products or breast milk on the packaging and labeling of their products provided to Injured Infant; and/or
- k. Representing that their cow's milk-based products have no serious side effects on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent when they knew or should have known the contrary to be true; and/or
- l. Representing that their cow's milk-based products have no serious side effects on the packaging and labeling of their products provided to Injured Infant when they knew or should have known the contrary to be true; and/or
- m. Representing that their cow's milk-based products were similar or equivalent to breast milk on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent when they knew or should have known the contrary to be true; and/or
- n. Representing that their cow's milk-based products were similar or equivalent to breast milk on the packaging and labeling of their products provided to Injured Infant when they knew or should have known the contrary to be true; and/or
- o. Representing that their cow's milk-based products were safe for premature infants on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent; and/or

- p. Representing that their cow's milk-based products were safe for premature infants on the packaging and labeling of their products provided to Injured Infant; and/or
- q. Representing that their cow's milk-based products were necessary for optimum growth on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent; and/or
- r. Representing that their cow's milk-based products were necessary for optimum growth on the packaging and labeling of their products provided to Injured Infant; and/or
- s. Representing that their products were based on up-to-date science, which made them safe for premature infants on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent; and/or
- t. Representing that their products were based on up-to-date science, which made them safe for premature infants on the packaging and labeling of their products provided to Injured Infant.

141. The Plaintiff Parent was not aware that these misrepresentations were false and justifiably relied on them. The Defendant Manufacturers' misrepresentations induced the Plaintiff Parent to allow their children to be fed Abbott's and Mead's infant products, in reliance on all the messaging they received about formula feeding, including, directly or indirectly, the Defendant Manufacturers' messaging. Had Abbott and Mead not committed these intentional misrepresentations, the Injured Infant would not have been exposed to the Defendant Manufacturers' unreasonably dangerous cow's milk-based products.

142. As a direct and proximate result, Abbott's and Mead's products were fed to the Injured

Infant, which caused and/or increased risk of their developing NEC and subsequent injuries.

143. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT V: NEGLIGENT MISREPRESENTATIONS
(Against Abbott and Mead)**

144. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth

herein.

145. At all times relevant to this action, the Injured Infant consumed the products at issue in their intended manner and for their intended purpose.

146. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide truthful, accurate, and complete information about the risks and benefits of using their products when used in the intended manner and for the intended purpose.

147. In the course of their business, Abbott and Mead breached their duty through misrepresentations made to consumers, in their advertising and promotional materials, as described in previous paragraphs and incorporated herein, each of whom were foreseeable recipients of this information.

148. Specifically, upon information and belief, Abbott and Mead made the following false statements of material fact on an ongoing and repeated basis to the public, including consumers, and parents like Plaintiff Parent and prior to the time the Injured Infant was fed their products:

- a. That their cow's milk-based products were safe and beneficial for premature infants when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or
- b. That their cow's milk-based products were necessary to the growth and nutrition of premature infants, when they knew or should have known that their products were not necessary to achieve adequate growth; and/or
- c. That their products have no serious side effects, when they knew or should have known the contrary to be true; and/or
- d. That cow's milk-based products were safe for premature infants; and/or

- e. That cow's milk-based products were necessary for optimum growth; and/or
- f. That cow's milk-based products were similar or equivalent to breast milk; and/or
- g. That their products were safe and more like breast milk than other infant products and that they had removed the harmful ingredients of cow's milk when, in fact, the cow's milk in their products was still capable of causing NEC, serious injury, and death; and/or
- h. That their products were safe for and provided better nutrition and growth to premature infants than donor milk, a non-cow's milk-based alternative to breast milk; and/or
- i. That their products can be fed with confidence to most of the preterm infants in the NICU and/or that premature infants would be happy and healthy or nourished and healthy on their products; and/or
- j. That their products were based on up-to-date science, which made them safe for premature infants; and/or
- k. Omitting the material fact that their products significantly increased the risk of NEC in premature infants, including omitting this material fact from their publicly available product information, marketing materials, and websites.

149. In addition to the above, Abbott and Mead, upon information and belief, also made the following false statements of material fact to Plaintiff Parent.

- a. Omitting from coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent that their products significantly increased the risk of NEC in premature infants; and/or

- b. Omitting from the packaging and labeling of their products provided to Injured Infant that their products significantly increased the risk of NEC in premature infants; and/or
- c. Representing that their cow's milk-based products were safe and beneficial for premature infants on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or
- d. Representing that their cow's milk-based products were safe and beneficial for premature infants on the packaging and labeling of their products provided to Injured Infant when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or
- e. Representing that their cow's milk-based products were necessary to the growth and nutrition of premature infants on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent when they knew or should have known that their products were not necessary to achieve adequate growth; and/or
- f. Representing that their cow's milk-based products were necessary to the growth and nutrition of premature infants on the packaging and labeling of their products provided to Injured Infant when they knew or should have known that their products were not necessary to achieve adequate growth; and/or

- g. Representing that their cow's milk-based products were similar or equivalent to breast milk on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent; and/or
- h. Representing that their cow's milk-based products were similar or equivalent to breast milk on the packaging and labeling of their products provided to Injured Infant; and/or
- i. Representing that their cow's milk-based products could be fed with confidence to premature infants and/or that premature infants would be healthy regardless of whether they were fed their cow's milk-based products or breast milk on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent; and/or
- j. Representing that their cow's milk-based products could be fed with confidence to premature infants and/or that premature infants would be healthy regardless of whether they were fed their cow's milk-based products or breast milk on the packaging and labeling of their products provided to Injured Infant; and/or
- k. Representing that their cow's milk-based products have no serious side effects on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent when they knew or should have known the contrary to be true; and/or
- l. Representing that their cow's milk-based products have no serious side effects on the packaging and labeling of their products provided to Injured Infant when they knew or should have known the contrary to be true; and/or

- m. Representing that their cow's milk-based products were similar or equivalent to breast milk on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent when they knew or should have known the contrary to be true; and/or
- n. Representing that their cow's milk-based products were similar or equivalent to breast milk on the packaging and labeling of their products provided to Injured Infant when they knew or should have known the contrary to be true; and/or
- o. Representing that their cow's milk-based products were safe for premature infants on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent; and/or
- p. Representing that their cow's milk-based products were safe for premature infants on the packaging and labeling of their products provided to Injured Infant; and/or
- q. Representing that their cow's milk-based products were necessary for optimum growth on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent; and/or
- r. Representing that their cow's milk-based products were necessary for optimum growth on the packaging and labeling of their products provided to Injured Infant; and/or
- s. Representing that their products were based on up-to-date science, which made them safe for premature infants on coupons, gift bags, other promotional materials, and the packaging and labeling of their product samples provided to Plaintiff Parent; and/or

- t. Representing that their products were based on up-to-date science, which made them safe for premature infants on the packaging and labeling of their products provided to Injured Infant.

150. Abbott and Mead were negligent or careless in not determining those representations to be false.

151. The Defendant Manufacturers' misrepresentations induced, and were intended to induce, the Plaintiff Parent to allow their child to be fed Abbott's and Mead's infant products, in justifiable reliance on all the messaging they received about formula feeding, including, directly or indirectly, the Defendant Manufacturers' messaging. Had Abbott and Mead not committed these negligent misrepresentations, the Injured Infant would not have been exposed to their unreasonably dangerous cow's milk-based products.

152. As a direct and proximate result, Abbott's and Mead's products were fed to the Injured Infant, which caused and/or increased of their developing NEC and subsequent injuries.

153. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;

- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT VI: FAILURE TO WARN
(Against Penn Medicine and Pennsylvania Hospital)**

154. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

155. Penn Medicine and Pennsylvania Hospital as purchaser, supplier, and/or distributor of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to purchase, supply, and distribute products that were free of unreasonable risk of harm when used in their intended manner and for their intended purpose, and/or to formulate, adopt, and enforce adequate rules and policies for the same.

156. At all times relevant to this action, the Injured Infant used the cow's milk-based products purchased, supplied, and/or distributed by Penn Medicine and Pennsylvania Hospital in their intended manner and for their intended purpose.

157. Penn Medicine and Pennsylvania Hospital employed or contracted with the healthcare professionals and medical staff at Pennsylvania Hospital, managing these individuals during their

treatment of the Injured Infant.

158. Penn Medicine and Pennsylvania Hospital negligently, outrageously, and recklessly supplied and distributed the Defendant Manufacturers' milk-based infant feeding products to these healthcare professionals and medical staff for use on premature infants, including the Injured Infant.

159. Moreover, at all relevant times, Penn Medicine and Pennsylvania Hospital knowingly authorized the Defendant Manufacturers' sales representatives to market, advertise, distribute, and/or sell their products at Pennsylvania Hospital. The Defendant Manufacturers' sales representatives were encouraged to interact with Pennsylvania Hospital's healthcare professionals and medical staff. These interactions provided the Defendant Manufacturers' sales representatives an opportunity to co-opt Pennsylvania Hospital's healthcare professionals and medical staff into assisting with the marketing, distribution, and/or sale of the Defendant Manufacturers' unreasonably dangerous products to consumers, such as the Plaintiff Parent.

160. Penn Medicine and Pennsylvania also knowingly, and intentionally, allowed the Defendant Manufacturers' sales representatives to routinely misrepresent the risks and benefits of Defendants' products to Pennsylvania Hospital's healthcare professionals and medical staff, including the misrepresentation that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

161. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known at the time that they acquired, distributed, and supplied the Defendant Manufacturers' cow's milk-based infant products that these products significantly increased the risk of NEC, serious injury, and death.

162. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, outrageously,

and recklessly, and breached its duty by:

- a. Failing to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in those babies; and/or
- b. Failing to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or
- c. Failing to warn or instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risk; and/or
- d. Failing to provide its healthcare professionals and medical staff with the well-researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or
- e. Failing to provide a warning in a method reasonably calculated/expected to reach the parents of newborns; and/or
- f. Failing to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products; and/or
- g. Failing to prevent the Defendant Manufacturers' sales representatives from misrepresenting to Pennsylvania Hospital's healthcare professionals and medical staff that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

163. Reasonable hospitals under the same or similar circumstances would have warned of the above risks, would have instructed their healthcare professionals and medical staff—as well as patients—on the safe use of the Defendant Manufacturers' products, and would have restricted the

ability of the Defendant Manufacturers' sales representatives to market the Defendant Manufacturers' unreasonably dangerous products without adequate warning.

164. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that its medical professionals and the parents of premature infants, including the Plaintiff Parent, would not have realized the risks associated with feeding cow's milk-based formula to premature infants.

165. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its duty to warn its medical providers and patients about the Defendant Manufacturers' unreasonably dangerous products, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

166. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital's failure to warn of the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

167. As a further direct and proximate result of Penn Medicine and Pennsylvania Hospital's failure to warn of the Defendant Manufacturers' unreasonably dangerous products, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against Penn Medicine and Pennsylvania Hospital, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained

as a result of Penn Medicine's conduct;

- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from Penn Medicine and Pennsylvania Hospital's oppressive, outrageous, reckless, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT VII: CORPORATE LIABILITY OF HEALTH-CARE PROVIDER
(Against Penn Medicine and Pennsylvania Hospital)**

168. Plaintiff incorporates by references each of the preceding paragraphs as if fully set forth herein.

169. At all relevant times, Penn Medicine and Pennsylvania Hospital owed a duty of care to the Injured Infant to ensure their safety and well-being while the Injured Infant was under the care of Pennsylvania Hospital staff. Specifically, Penn Medicine and Pennsylvania Hospital had a duty to the Injured Infant to formulate, adopt, and enforce adequate rules and policies to ensure quality care for the Injured Infant. Further, Penn Medicine and Pennsylvania Hospital owed a duty to the Injured Infant to oversee its healthcare professionals and medical staff that provided patient care to the Injured Infant.

170. Penn Medicine and Pennsylvania Hospital owed a duty to its patients, and the Injured Infant in particular, to formulate, adopt, and enforce adequate rules and policies for the purchase, supply,

distribution, and use of products that were free of unreasonable risk of harm when used in their intended manner and for their intended purpose and ensured quality care for the Injured Infant.

171. At all times relevant to this action, the Injured Infant used the cow's milk-based products purchased, supplied, and/or distributed by Penn Medicine and Pennsylvania Hospital in their intended manner and for their intended purpose.

172. Moreover, at all relevant times, Penn Medicine and Pennsylvania Hospital knowingly authorized the Defendant Manufacturers' sales representatives to market, advertise, distribute, and/or sell their products at Pennsylvania Hospital. The Defendant Manufacturers' sales representatives were encouraged to interact with Pennsylvania Hospital's healthcare professionals and medical staff. These interactions provided the Defendant Manufacturers' sales representatives an opportunity to co-opt Pennsylvania Hospital's healthcare professionals and medical staff into assisting with the marketing, distribution, and/or sale of the Defendant Manufacturers' unreasonably dangerous products.

173. Penn Medicine and Pennsylvania Hospital also knowingly allowed the Defendant Manufacturers' sales representatives to routinely misrepresent the risks and benefits of Defendants' products to Pennsylvania Hospital's healthcare professionals and medical staff, including the misrepresentation that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

174. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known at the time that it formulated, adopted, and enforced its rules for the acquisition, distribution, and supply of the Defendant Manufacturers' cow's milk-based infant products, including the access afforded the Defendant Manufacturer's sales representatives, that these products significantly increased the risk of NEC, serious injury, and death for premature infants.

175. Since prior to 2000, Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that premature babies are increased risk for NEC.

176. Since prior to 2000, Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that NEC increases the risk of permanent injury and death.

177. Since 2000, Penn Medicine and Pennsylvania Hospital knew or reasonably should have known prior to that human milk (mother's milk) was safest and best for premature infants.

178. Since 2000, Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that human milk (mother's milk) decreased the risk of NEC, serious injury, and death for premature infants.

179. By no later than 2012, Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that donor human milk decreased the risk of NEC, serious injury, and death for premature infants.

180. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that its medical professionals and the parents of premature infants, including the Plaintiff Parent, would not have realized the risks associated with feeding cow's milk-based formula to premature infants.

181. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, outrageously, and recklessly, and breached its duty by:

- a. Failing to formulate, adopt, and enforce adequate rules and policies that would have required human milk (mother's milk and/or donor milk) to be recommended to premature babies; and/or
- b. Failing to formulate, adopt, and enforce adequate rules and policies that would have restricted or prevented the use of cow's milk-based products for feeding premature babies; and/or

- c. Failing to formulate, adopt, and enforce adequate rules and policies that informed the Plaintiff Parent that human milk (mother's milk and/or donor milk) significantly decrease the risk of NEC, severe injury, and death in premature babies, like the Injured Infant; and/or
- d. Failing to formulate, adopt, and enforce adequate rules and policies that warned the Plaintiff Parent that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in premature babies, like the Injured Infant; and/or
- e. Failing to formulate, adopt, and enforce adequate rules and policies that discussed the risks of cow's milk-based products significantly increasing the risk of NEC, severe injury, and death in premature babies, like the Injured Infant; and/or
- f. Failing to formulate, adopt, and enforce adequate rules and policies that warned its healthcare professionals and medical staff that cow's milk-based products are unsafe and/or contraindicated for premature babies like the Injured Infant; and/or
- g. Failing to formulate, adopt, and enforce adequate rules and policies to instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risk; and/or
- h. Failing to formulate, adopt, and enforce adequate rules and policies to provide its healthcare professionals and medical staff with the well-researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or
- i. Failing to formulate, adopt, and enforce adequate rules and policies to ensure a

warning in a method reasonably calculated/expected to reach the parents of premature newborns, like the Plaintiff Parent; and/or

- j. Failing to formulate, adopt, and enforce adequate rules and policies to prevent the Defendant Manufacturers' sales representative from misrepresenting to Pennsylvania Hospital's healthcare professionals and medical staff that premature babies would not grow adequately with human milk and human milk products and/or that use of donor milk was not advised for premature infants; and/or
- k. Failing to establish a donor milk program that was sufficient to meet the needs of the premature babies, like the Injured Infant.
- l. Failing to formulate, adopt, and enforce adequate rules and policies regarding the feeding of premature infants leaving it to the discretion of the medical team and parent without a discussion of risks and benefits.
- m. Allowing parental preference to be the standard for feeding premature infants;
- n. Failing to follow the American Academy of Pediatrics recommendations relating to feeding premature infants;
- o. Failing to follow the American Academy of Pediatrics recommendations to use donor milk if mother's milk was unavailable instead of cow's milk-based products;
- p. Failing to recommend donor milk if mother's milk was unavailable by no later than 2012; and
- q. Failing to transfer to a hospital by no later than 2012 where donor milk was available if there was no donor milk available.

182. A reasonable hospital under the same or similar circumstances would have formulated, adopted, and enforced adequate policies, and rules to restrict the feeding of cow's milk-based

products to premature babies, including developing an adequate donor milk program, instructing its healthcare professionals and medical staff on the safe use of Defendants Manufacturers' cow's milk-based products, and restricting the marketing of the Defendant Manufacturers' unreasonably dangerous products to its healthcare professionals, medical staff, and parents of premature infants under its care.

183. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its duty to formulate, adopt, and enforce adequate rules and policies to ensure the quality care of its patients, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

184. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital failure to formulate and enforce adequate policies and rules related to the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

185. As a further direct and proximate result of Penn Medicine and Pennsylvania Hospital negligent, reckless, and outrageous conduct the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

186. In the alternative, Penn Medicine and Pennsylvania Hospital owed a duty to its patients, and the Injured Infant in particular, to oversee the practicing healthcare professionals and medical staff that provided the products at issue to infants under Pennsylvania Hospital's care, including the Injured Infant.

187. Penn Medicine and Pennsylvania Hospital employed or contracted with the healthcare

professionals and medical staff at Pennsylvania Hospital and was responsible for overseeing those individuals during their treatment of the Injured Infant.

188. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, recklessly, and outrageously breached its duty by:

- a. Failing to oversee its healthcare professionals and medical staff on their use of cow's milk-based products for feeding premature babies; and/or
- b. Failing to warn or instruct its healthcare professionals and medical staff that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in those babies; and/or
- c. Failing to warn or instruct its healthcare professionals and medical staff that cow's milk-based products are unsafe and/or contraindicated for premature babies like the Injured Infant; and/or
- d. Failing to oversee its healthcare professionals and medical staff to restrict their feeding of cow's milk-based products to premature babies; and/or
- e. Failing to warn or instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risk; and/or
- f. Failing to provide its healthcare professionals and medical staff with the well-researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or
- g. Failing to provide its healthcare professionals and medical staff with warnings about the dangers of the Defendants' Manufacturers products in a method

reasonably calculated/expected to reach the parents of newborns; and/or

- h. Failing to provide statistical evidence to its healthcare professionals and medical staff showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products; and/or
- i. Failing to oversee its healthcare professionals and medical staff to ensure that the Defendant Manufacturers' sales representatives' misrepresentations that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants had not influenced the use and/or misuse of the Defendant Manufacturers' products.

189. A reasonable hospital under the same or similar circumstances would have warned of the above risks, would have instructed its healthcare professionals and medical staff on the safe use of the Defendant Manufacturers' products, and would have restricted the ability of the Defendant Manufacturers' sales representatives to market the Defendant Manufacturers' unreasonably dangerous products without adequate warning.

190. A reasonable hospital under the same or similar circumstances would have overseen and managed its healthcare professionals and medical staff to ensure that they received proper training and updating on the risks associated with feeding cow's milk-based formula to premature infants.

191. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its duty to oversee its healthcare professionals and medical staff who provide patient care, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

192. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital's failure to oversee its healthcare professionals and medical staff on the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the

Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

193. As a further direct and proximate result of Penn Medicine and Pennsylvania Hospital's negligent and reckless conduct, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against Penn Medicine and Pennsylvania Hospital, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of Penn Medicine and Pennsylvania Hospital's conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from Penn Medicine's oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

DEMAND FOR JURY TRIAL

194. Plaintiff hereby demands a jury trial for all claims triable.

Dated: July 16, 2024

Respectfully submitted,

KLINE & SPECTER, P.C.

By: /s/ Tobias L. Millrood
Tobias L. Millrood, Esq.
Elizabeth A. Crawford, Esq.
Timothy A. Burke, Esq.
John P. O'Neill, Esq.

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Attorneys for Plaintiffs

EXHIBIT A-70

KLINE & SPECTER, P.C.

By:

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Attorney for Plaintiffs

IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
TRIAL DIVISION - CIVIL

ALICE STILLIS, ON HER OWN BEHALF
AND AS PARENT AND NATURAL
GUARD OF M.E., A MINOR.

Plaintiff,

v.

MEAD JOHNSON & COMPANY, LLC,
et al.

Defendants.

MARCH Term, 2022

No. 02617

JURY TRIAL DEMANDED

PRAECIPE TO ATTACH VERIFICATION TO SECOND AMENDED COMPLAINT

Please attach Plaintiff's Verifications to the Second Amended Complaint filed of record on July 17, 2024, with regard to the above-captioned matter.

Respectfully submitted,

KLINE & SPECTER, P.C.

Dated: September 6, 2024

/s/ Timothy A. Burke
TIMOTHY A. BURKE, ESQ.
Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on September 6, 2024, I caused a true and correct copy of the foregoing document to be served by electronic filing to all counsel of record.

Dated: September 6, 2024

/s/ Timothy A. Burke
TIMOTHY A. BURKE

VERIFICATION

I, Alice Stills, verify that the statements made in Plaintiff's Second Amended Complaint are true and correct to the best of my knowledge, information, and belief. I understand that false statements made herein are subject to the penalties of 18 Pa. C.S. § 4904, relating to unsworn falsification to authorities.

Date: 07/24/2024

By: 

EXHIBIT A-71

FILED

19 AUG 2024 05:02 pm

Civil Administration

M. RIVERA

**IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
TRIAL DIVISION – CIVIL SECTION**

ALICE STILLIS, *on her own behalf and as Parent
and Natural Guardian of M.E., a Minor,*

Plaintiffs,

v.

MEAD JOHNSON & COMPANY LLC; MEAD
JOHNSON NUTRITION COMPANY; ABBOTT
LABORATORIES; THE PENNSYLVANIA
HOSPITAL OF THE UNIVERSITY OF
PENNSYLVANIA HEALTH SYSTEM, *d/b/a*
PENNSYLVANIA HOSPITAL; and THE
TRUSTEES OF THE UNIVERSITY OF
PENNSYLVANIA, *d/b/a* PENN MEDICINE,

Defendants.


: PHILADELPHIA COUNTY
: COURT OF COMMON PLEAS
: TRIAL DIVISION

: MARCH TERM, 2022
: No. 220302617

ORDER

AND NOW, this 17th day of September, 2024, upon consideration of the Motion for Admission of Attorney Catherine T. Zeng *Pro Hac Vice*, it is hereby **ORDERED** and **DECREED** that the Motion for Admission *Pro Hac Vice* is hereby **GRANTED**, and Catherine T. Zeng, of Jones Day, is hereby admitted *Pro Hac Vice* for the purpose of representing Defendant Abbott Laboratories in the above-captioned action after obtaining the appropriate City of Philadelphia Business Privilege Tax License pursuant to 19-2602 of the Philadelphia Code. *Pro Hac Vice* Counsel shall pay all City Business and Wage Tax as required.

BY THE COURT:


J.

ORDER-Stillis Etal Vs Mead Johnson Nutrition Company Etal [FJB]



22030261700141

Case ID: 220302617
Control No.: 24084167

EXHIBIT A-72

Alice Stills, on her own behalf and as Parent and
Natural Guardian of M.E., a minor

Plaintiffs

v.

MEAD JOHNSON & COMPANY, LLC, et al.

Defendants.

COURT OF COMMON PLEAS
PHILADELPHIA COUNTY, PENNSYLVANIA

CIVIL DIVISION

MARCH TERM, 2022
NO. 2617



ORDER

AND NOW, this 27th day of Oct 2024, upon consideration of the Preliminary Objections of Defendants the Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital and the Trustees of the University of Pennsylvania d/b/a Penn Medicine to Plaintiffs' Second Amended Complaint, and any Response thereto, it is hereby **ORDERED** that the Preliminary Objections are **SUSTAINED**. It is further **ORDERED** that all claims against Defendants the Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital and the Trustees of the University of Pennsylvania d/b/a Penn Medicine are hereby **DISMISSED** with prejudice.

BY THE COURT:

J.

(See footnote to # 220302583
24081569)

ORDER-Stills Etal Vs Mead Johnson Nutrition Company Etal [FJB]



22030261700144

Case ID: 220302617
Control No.: 24081574